

**No. 31015/10/2017-Pricing**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhawan,  
New Delhi 110 001

**Subject: Two Review applications of M/s Neon Laboratories Limited against price fixation of their formulations "Midazolam Injection 5mg/ml and Midazolam Injection 1mg/ml" vide NPPA order No. S.O. 4128(E), dated 22.12.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Two Review applications dated 06.01.2017.  
2) NPPA notification under review S.O. No.4128(E), dated 22.12.2016  
3) Record Note of discussions held in the personal hearing on 22.8.2017.**

1. These are two review petitions under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Neon Laboratories Limited (hereinafter called the petitioner) against notification S.O. No.4128(E), dated 22.12.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Midazolam Injection 5mg/ml and Midazolam Injection 1mg/ml

2. The petitioner has contended as under:

**I. In respect of Midazolam Injection 5 mg/ml:-**

(i) The worksheet for calculation of ceiling price of formulations notified vide S.O. 4128(E) dated 22<sup>ND</sup> December, 2016 failed to consider their two SKUs namely; MEZOLAM INJECTION 5ML VIAL containing Midazolam 5mg/ml and MEZOLAM INJECTION 10ML VIAL containing Midazolam 5mg/ml having Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% Market Share. Against the total MAT value considered of INR. 265.87 lakhs their formulations have the MAT value of INR. 236.36 lakhs.

(ii) AND WHEREAS, the company has submitted a certificate from Chartered Accountant to certify that MEZOLAM INJECTION 5ML VIAL and MEZOLAM INJECTION 10ML VIAL has Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% Market Share, constituting 47.06% of the total MAT Value.

(iii) AND WHEREAS, NPPA has further erred by considering their formulation MEZOLAM 5 MG INJECTION 5 ML which contains Midazolam 5MG/5ML in the calculation of ceiling price of Midazolam 5MG/ML.

II. **In respect of Midazolam Injection 1 mg/ml:-**

(i) The worksheet for calculation of ceiling price of formulations notified vide S.O. 4128 (E) dated 22<sup>ND</sup> December, 2016 failed to consider their two SKUs namely; MEZOLAM INJECTION 5ML VIAL containing Midazolam 5mg/ml and MEZOLAM INJECTION 10ML VIAL containing Midazolam 10mg/10ml having Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% Market Share. Against the total MAT value considered of INR. 362.25 lakhs their formulations have the MAT value of INR. 1438.65 lakhs.

(ii) AND WHEREAS, the company has submitted a certificate from Chartered Accountant to certify that MEZOLAM INJECTION 5ML VIAL and MEZOLAM INJECTION 10ML VIAL has Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% Market Share, constituting 79.89% of the total MAT Value.

3. AND WHEREAS, Para 4 of DPCO, 2013 clearly states that the government shall include Prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of Moving Annual Turnover of that medicine.

**Under the circumstances:**

a. NPPA should revise the ceiling price for Midazolam 5MG/ML and Midazolam 1MG/ML under the provisions of Para 4 of DPCO, 2013.

b. NPPA must consider their formulations, having Market share greater than 1% based on MAT of August, 2015, for arriving at the ceiling price for captioned formulation.

c. All pack sizes/SKUs having Market share less than 1% must not be considered in the calculation of ceiling price under Para 4.

4. In view of above company requested this Department as under:-

a. To consider and conclude that NPPA had erred in pricing of Midazolam 5MG/ML and Midazolam 1MG/ML under Notification no. S.O 4128(E) dated 22<sup>ND</sup> December, 2016.

b. To direct NPPA to include our SKUs in revising the ceiling price of Midazolam 5MG/ML and Midazolam 1MG/ML under the provisions of Para 4 of DPCO, 2013.

c. Pass a speaking order in respect hereof.

d. Any other order in interest of this manufacturer.

3. **Comments of NPPA:**

In this regard, it is mentioned that ceiling price of Rs.13.46/ml for Midazolam 5mg/ml Injection and Rs.5.48/ml for Midazolam 1mg/ml Injection was notified vide S.O. 4128(E) dated 22.12.2016 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

2. Company has stated that correct methodology was not followed in arriving at the ceiling price for Midazolam 5mg/ml Injection & Midazolam 1mg/ml Injection. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013 and as per the decisions of 27<sup>th</sup> Authority meeting held on 29.3.2016. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has pointed out that NPPA has not included the PTR & MAT value of their product Midazolam 5mg/ml Injection & Midazolam 1mg/ml Injection in 5ml & 10ml vial for computing the ceiling price of Midazolam 5mg/ml Injection & Midazolam 1mg/ml Injection.	NPPA has fixed the ceiling price for Midazolam 5mg/ml Injection & Midazolam 1mg/ml Injection as per the data provided by pharma-trac for the month of August, 2015. M/s Neon Laboratories Ltd. <u>did not make</u> any representation against the proposed draft ceiling price uploaded on NPPA's website.

4. During the personal hearing, the representative of the petitioner company made no further submission in addition to the original petition by the company. In reply, NPPA representatives have also made no further comments.

5. **Examination:**

**Midazolam Injection 5mg/ml:-**

The company submitted that their two formulations, viz. MEZOLAM INJECTION 5ML VIAL containing Midazolam 5mg/ml and MEZOLAM INJECTION 10ML VIAL containing Midazolam 5mg/ml having Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% Market Share. In support of their claim, the Company has submitted only a certificate from Chartered Accountant Firm M/s M.S.J. & Co., dated 6.1.2017 (page 12/cors) along with their review application. However, on going through the CA certificate, it is seen that there is only one formulation Mezolam 1ml Amp containing Midazolam 5mg./ml having MAT value of Rs.236.35 lacs for the period September, 2014 to August, 2015. In view of this, NPPA may be directed to examine the documentary proof submitted by the company and may ask for other necessary documentary proof required to verify the claim of the company about actual MAT value and market share of their product Mezolam 1ml Amp containing Midazolam 5mg./ml, and after verification, re-fix the price of Midazolam 5mg/ml, on merit.

**Midazolam Injection 1mg/ml:-**

The company submitted that their two formulations, viz. MEZOLAM INJECTION 5ML VIAL containing Midazolam 5mg/5ml and MEZOLAM INJECTION 10ML VIAL containing Midazolam 10mg/10ml having Moving Annual Turnover (MAT) for the period

ending August, 2015 of greater than 1% Market Share. In support of their claim, the Company has submitted only a certificate from Chartered Accountant Firm M/s M.S.J. & Co., dated 6.1.2017 (page 1/cors) along with their review application. However, on going through the CA certificate, it is seen that there are two formulations Mezolam 10ml vial containing Midazolam 1mg./1ml and Mezolam 5ml vial containing Midazolam 1mg/1ml having MAT value of Rs.888.08 lacs and Rs.550.57 lacs for the period September, 2014 to August, 2015. In view of this, NPPA may be directed to examine the documentary proof submitted by the company and may ask for other necessary documentary proof required to verify the claim of the company about actual MAT value and market share of their products Mezolam 10ml vial containing Midazolam 1mg./1ml and Mezolam 5ml vial containing Midazolam 1mg/1ml, and after verification, re-fix the price of Midazolam 1mg/ml, on merit.

6. **Government Decision:**

**“NPPA is hereby directed to examine the documentary proof submitted by the company and may ask for other necessary documentary proof required to verify the claim of the company about actual MAT value and market share of their product Mezolam 1ml Amp containing Midazolam 5mg./ml, and after verification, re-fix the price of Midazolam 5mg/ml, on merit.”**

**“NPPA is further directed to examine the documentary proof submitted by the company and may ask for other necessary documentary proof required to verify the claim of the company about actual MAT value and market share of their products Mezolam 10ml vial containing Midazolam 1mg./1ml and Mezolam 5ml vial containing Midazolam 1mg/1ml, and after verification, re-fix the price of Midazolam 1mg/ml, on merit.”**

Issued on this date, the 30th day of October, 2017.

**(M.K. Bhardwaj)**  
**Deputy Secretary**  
**For and on behalf of the President of India**

To

1. **M/s. Neon Laboratories Limited,  
140, Damji Shamji Ind. Complex,  
M. Caves Road, Andheri (E),  
Mumbai-400 093.**
2. **The Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building, New Delhi-110001**

Copy to :

1. **PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
2. **PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
3. **T.D., NIC for uploading the order on Department's Website**