

**No. 31015/11/2017-Pricing**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhawan,  
New Delhi 110 001

**Subject: Review application of M/s Neon Laboratories Limited against price fixation of their formulation "Methylprednisolone Injection 40mg/ml" vide NPPA order No. S.O. 248(E), dated 24.01.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Review application dated 31.01.2017**  
**2) NPPA notification under review S.O. No.248(E), dated 24.01.2017**  
**3) Record Note of discussions held in the personal hearing on 22.8.2017.**

1. This is a review petition 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.248(E), dated 24.01.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Methylprednisolone Injection 40mg/ml.

2. The petitioner has contended as under:

I. The worksheet for calculation of ceiling price of formulations notified vide S.O. 248 (E) dated 24th January, 2017 failed to consider their formulation namely; NEODROL 40 MG VIAL" Containing Methylprednisolone 40 MG/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. 4667.82 lakhs their formulation has the MAT value of INR. 113.84 lakhs (and not INR. 12.93 Lakhs) being 2.43% of total MAT value.

II. AND WHEREAS, they referred to NPPA's Notification dated 26th October, 2016 vide O.M. No. 8(34)/2016/DP/NPPA/Div.II in connection with Draft version of Proposed Price Calculation, had also failed to consider their formulation namely; NEODROL 40 MG VIAL Containing Methylprednisolone 40 MG/ML despite having Moving Annual Turnover (MAT) of greater than for the period ending August, 2015 of greater than 1% Market Share.

III. AND WHEREAS, Neon submitted a Letter to NPPA dated 10th November 2016, against the aforesaid Notification O.M. No. 8(34)/2016/DP/NPPA/Div.II dated 26th October, 2016 within the prescribed time of 10 working days.

IV. AND WHEREAS, NPPA vide letter F.No. 7(49)/2016/DP/NPPA/Div- II dated 16<sup>th</sup> November, 2016 as received by company on 21<sup>st</sup> November, 2016, requested further data along with supporting documents. Company replied on

24th November, 2016 to the aforesaid Letter dated 16th November, 2016 vide F.No. 7(49)/2016/DP/NPPA/Div-II furnishing all the requisite data as required by NPPA within the prescribed time limit.

- V. AND WHEREAS, NPPA has further erred by not considering their formulation NEODROL 40 Mg Vial which contains Methylprednisolone 40 MG/ML in the calculation of ceiling price of Methylprednisolone Injection 40 MG/ML despite submission of Neon's documentary evidence.
- VI. 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 Methylprednisolone 40 MG/ML under the provisions of Para 4 of DPCO, 2013.
- b. NPPA must consider their formulation NEODROL 40 Mg Vial which contains Methylprednisolone 40 MG/ML, having Market share greater than 1% based on MAT of August, 2015, which is 2.43% and MAT value is 113.84 Lakhs 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.

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

- a. To consider and conclude that NPPA had erred in pricing of METHYLPREDNISOLONE 40 MG/ML under Notification no. S.O. 248 (E) dated 24<sup>th</sup> January, 2017 as per the provisions of Para 4 of DPCO, 2013.
- b. To direct NPPA to include their SKU in revising the ceiling price of METHYLPREDNISOLONE 40 MG/ML under the provisions of Para 4 of DPCO, 2013 by including the PTR of their formulation "Neodrol 40MG vial".

- c. Pass a speaking order in respect hereof.
- d. Any other order in interest of this manufacturer

3. **Comments of NPPA:**

Ceiling price of Rs. 44.53/ml for **Methylprednisolone 40mg/ml Injection** was notified vide S.O. 248(E) dated 24.01.2017 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 **Methylprednisole 40mg/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 Neodrol 40mg vial containing Methylprednisole <b>40mg/ml</b> despite having Moving Annual Turnover higher than 1% market share. Company has also submitted the representation against non-inclusion of their product Neodrol 40mg vial in the working sheet within the prescribed time of 10 working days required as DOP vide letter no. F. No. 31015/44/2016-PI.I dated 11.7.2016.	NPPA has fixed the ceiling price for <b>Methylprednisole 40mg/ml Injection</b> as per the data provided by pharmaTrac for the month of August, 2015. The product of M/s Neon Lab. was not included in the calculation of ceiling price of Methylprednisolone 40mg/ml injection, since, it had less than 1% market share as per PharmaTrac data. The representation of M/s Neon Lab. Ltd. was sent to PharmaTrac for confirmation. PharmaTrac in its reply indicated the same MAT value of the company's product as indicated in its original data. The company, however, in its representation did not give any documentary proof regarding the MAT value as claimed by them. Accordingly, the same was not considered by the Authority.

3. Company has not challenged any notification in respect of **Methylprednisole 40mg/ml Injection** in the Court.

4. During the personal hearing, the representative of the petitioner company made no further submission in addition to the original petition.

## **5. Examination:**

On going through the calculation sheet, it is seen that the MAT value of NEODROL 40MG Vial which contains Methylprednisolone Injection 40mg/ml of the company is shown as Rs.12.93 lakhs, having 0.28% market share, whereas the company claims the MAT value of Rs.113.84 lakhs, having 2.43% market share. NPPA stated that the representation of M/s Neon Lab. Ltd. was sent to PharmaTrac for confirmation, but the claim of the company was not accepted by PharmaTrac. As stated by NPPA, the company, in its representation, did not give any documentary proof regarding the MAT value as claimed by them. During the personal hearing also, the company did not submit any documentary proof in support of its claim. In the absence of any documentary proof, the claim of the company cannot be accepted.

5.2 However, on perusal of the calculation sheet, it is observed that NPPA has taken into account one formulation DEPO MEDROL 40MG Injection 5ml of Pfizer Ltd., having MAT value of less than 1% (only 0.11% of market share). In view of this, NPPA may be directed to consider MAT value of only six formulations out of seven, having MAT value of more than 1% market share, as DPCO does not recognize a company for average PTR but only medicines / formulations.

## **6. Government Decision:**

**“The claim of the company, that their product NEODROL 40MG Vial which contains Methylprednisolone Injection 40mg/ml is having 2.43% market share of total MAT value, cannot be considered in the absence of any supportive documentary proof.”**

**“However, NPPA is directed to consider MAT value of only six formulations out of seven, having MAT value of more than 1% market share, as DPCO does not recognize a company for average PTR but only medicines / formulations.”**

Issued on this date of 28<sup>th</sup> day of September, 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 Indl. 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**