

**No. 31015/12/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Three Review applications of M/s Neon Laboratories Limited against price fixation of their formulations “Sodium Bicarbonate Injection – 8.4%, Lignocaine-2% + Adrenaline-1:20000 (5mcg/ml) and Adenosine 3mg/ml.” vide NPPA order No. S.O. 443(E), dated 14.2.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Three Review applications dated 21.02.2017 and 22.2.2017.
2) NPPA notification under review S.O. No.443(E), dated 14.2.2017
3) Record Note of discussions held in the personal hearing on 22.8.2017.

1. These are three 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.443(E), dated 14.2.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Sodium Bicarbonate Injection – 8.4%, Lignocaine-2% + Adrenaline-1:20000 (5mcg/ml) and Adenosine 3mg/ml.

2. The petitioner has contended as under:

I. In respect of SODIUM BICARBONATE INJECTION-8.4%:-

(i) The worksheet for calculation of ceiling price of formulations notified vide S.O. 443 (E) dated 14th February, 2017 **failed to consider the Accurate Price to Retailer (PTR) for their Formulation** namely; “SODAC”, containing SODIUM BICARBONATE INJECTION-8.4% having Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% of Market Share.

(ii) AND **WHEREAS, the price to retailer of SODAC was erroneously considered as INR 25.00 instead of the August 2015 Price to Retailer of INR 29.15.**

(iii) AND WHEREAS, the company had written letter to NPPA requesting correction to the draft price calculation sheet of Sodium Bicarbonate-8.4% within the prescribed time of 10 days from the issue of O.M. No. 8(34)/2016/DP/NPPA/Div.II dated 04th January 2017. NPPA requested further data along with supporting documents. Neon replied on 9th February, 2017 to the aforesaid Letter dated 31st January, 2017 furnishing all the requisite data as required by NPPA within the prescribed time limit.

WHEREAS, despite above submission NPPA has not considered the company's formal requests for correction of the error in price calculation sheet used in the calculation ceiling prices of their aforesaid formulations.

Under the circumstances:

a. The Price to Retailer for SODAC, was erroneously considered to INR 25.00 instead of INR 29.15 despite submission of all relevant document for price correction from the manufacturer as required.

b. NPPA has failed to act despite timely submission of required supporting documents/information relating to Price to Retailer (PTR) and Moving Annual Turnover (MAT) data for the month of August 2015 required for correction in proposed price Calculation Sheets for Proposed revised/notified ceiling price/retail price on NPPA's website.

(iv). In view of above company requested this Department as under:-

a. To consider and conclude that Ceiling Price of "SODIUM BICARBONATE INJECTION-8.4%" as notified vide S.O 443(E) dated 14th February, 2017 is incorrect and needs to be rectified.

b. To direct NPPA to notify the correct prices of SODIUM BICARBONATE INJECTION-8.4% within 15 days to avoid further undue punishment to the company.

c. Pass a speaking order in respect hereof.

d. Any other order in interest of this manufacturer

II. In respect of LIGNOCAINE-2% + ADRENALINE-1:200000(5MCG/ML):-

(i) the worksheet for calculation of ceiling price of formulations notified vide S.O. 443 (E) dated 14th February, 2017 failed to consider the Accurate Price to Retailer (PTR) for their Formulation namely; "LOX 2% with ADRENALINE" Containing Lignocaine-2% + Adrenaline- 1:200000(5mcg/ml) having Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% of Market Share.

(ii) AND WHEREAS, the price to retailer of LOX 2% with ADRENALINE was erroneously considered as INR 22.00 instead of the August 2015 Price to Retailer of INR 24.43.

(iii) WHEREAS, the company had written letter to NPPA requesting correction to the draft price calculation sheet of Lignocaine-2% + Adrenaline- 1:200000(5mcg/ml) within the prescribed time of 10 days from the issue of O.M. No. 8(34)/2016/DP/NPPA/Div.II dated 04th January 2017.

(iv) AND WHEREAS, NPPA requested further data along with supporting documents. Neon replied to the Letter furnishing all the requisite data as required by NPPA within the prescribed time limit. Despite above submission NPPA has not considered company's formal requests for correction of the error in price calculation used in the calculation ceiling prices of the aforesaid formulations.

Under the circumstances:

a. **The Price to Retailer for Lox 2% With Adrenaline, was erroneously considered to INR 22.00 instead of INR 24.43 despite submission of all relevant document for price correction from the manufacturers as required.**

b. NPPA has failed to act despite timely submission of required supporting documents/information relating to Price to Retailer (PTR) and Moving Annual Turnover (MAT) data for the month of August 2015 required for correction in proposed price Calculation Sheets for Proposed revised/notified ceiling price/retail price on NPPA's website.

(v). In view of above company requested this Department as under:-

a. To consider and conclude that Ceiling Price of 'LIGNOCAINE-2% + ADRENALINE- 1:200000(5MCG/ML)" as notified vide S.O 443(E) dated 14th February, 2017 is incorrect and needs to be rectified.

(b) To direct NPPA to notify the correct prices of LIGNOCAINE-2% + ADRENALINE-1:200000(5MCG/ML) within 15 days to avoid further undue punishment to the company.

c. Pass a speaking order in respect hereof.

d. Any other order in interest of this manufacturer

III. In respect of ADENOSINE 3 MG/ML:-

(i) The worksheet for calculation of ceiling price of formulations notified vide S.O. 443 (E) dated 14th January, 2017 failed to consider their Formulation namely; "ADNEON 2ML AMP" Containing Adenosine 3 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. 97.91 lakhs their formulation has the MAT value of INR. 80.68 lakhs being 45% of total MAT value.

(ii) AND WHEREAS, Neon submitted a Letter to NPPA against the Notification O.M. No. 8(34)/2016/DP/NPPA/Div.II dated 26th October, 2016 within the prescribed time of 10 working days. NPPA requested further data along with supporting documents. Neon replied to the Letter furnishing all the requisite data as required by NPPA within the prescribed time limit.

(iii) AND WHEREAS, NPPA has further erred by not considering their formulation ADNEON 2ML AMP which contains Adenosine 3 mg/ml in the calculation of ceiling price Adenosine Injection 3 mg/ml despite submission of Neon's documentary evidence.

(iv) 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 Adenosine Injection 3 mg/ml under the provisions of Para 4 of DPCO, 2013.

b. NPPA must consider company's formulation ADNEON 2ML AMP which contains Adenosine 3mg/ml, having Market share greater than 1% based on MAT of August, 2015, which is 45% and MAT value is 80.68 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.

(v). In view of above company requested this Department as under:-

a. To consider and conclude that NPPA had erred in pricing of ADNEON 2ML AMP under Notification no. S.O. 443 (E) dated 14th February, 2017 as per the provisions of Para 4 of DPCO, 2013.

b. To direct NPPA to include their Formulation in revising the ceiling price of Adenosine Injection 3 mg/ml under the provisions of Para 4 of DPCO, 2013 by including the PTR of their formulation "ADNEON 2ML AMP".

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. 1.20/ml for **Sodium Bicarbonate 8.4% Injection**, Rs. 0.85/ml for **Lignocaine-2% + Adrenaline – 1:20000 (5mcg/ml)** and Rs. 82.75/ml for **Adenosine 3mg/ml** was notified vide S.O. 443(E) dated 14.02.2017 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

3.2 Company has stated that correct methodology was not followed in arriving at the ceiling price for **Sodium Bicarbonate 8.4% Injection, Lignocaine-2% + Adrenaline – 1:20000 (5mcg/ml) and Adenosine 3mg/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 27th Authority meeting held on 29.3.2016. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
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1.	<p>Sodium Bicarbonate 8.4% Injection- NPPA has not considered actual PTR of their product Sodac Injection while computing the ceiling price for Sodium Bicarbonate Injection.</p> <p>II. Their representation to revise the ceiling price for Sodium Bicarbonate 8.4% Injection was also not considered by NPPA.</p>	<p>NPPA has fixed the ceiling price for Sodium Bicarbonate 8.4% Injection as per the data provided by pharma-trac for the month of August, 2015.</p> <p>Company did not submit the requisite information / data required as per OM no. 8(34)/2016/Div.II/DP/NPPA dated 10.10.2016. Further, company has not complied with IPDMS up to 100%, therefore, their representation was not considered by the Authority.</p>
2.	<p>Lignocaine-2% + Adrenaline – 1:20000 (5mcg/ml) – Company has pointed out that NPPA has considered the PTR Rs. 22.00 against the actual PTR Rs. 24.43 for their product LOX 2% with Adrenaline.</p> <p>II. Their representation to revise the ceiling price for Lignocaine-2% + Adrenaline – 1:20000 (5mcg/ml) was also not considered by NPPA.</p>	<p>NPPA has fixed the ceiling price for Lignocaine-2% + Adrenaline – 1:20000 (5mcg/ml) as per the data provided by pharma-trac for the month of August, 2015.</p> <p>Company did not submit the requisite information / data required as per OM no. 8(34)/2016/Div.II/DP/NPPA dated 10.10.2016. Further, company has not complied with IPDMS up to 100%, therefore, their representation was not considered by the Authority.</p>
3.	<p>Adenosine 3mg/ml Injection – Company has pointed out that NPPA has not included the PTR & MAT value while computing the ceiling price for Adenosine 3mg/ml Injection.</p> <p>II. Their representation to revise the ceiling price for Adenosine 3mg/ml Injection was also not considered by NPPA.</p>	<p>NPPA has fixed the ceiling price for Adenosine 3mg/ml Injection as per the data provided by pharma-trac for the month of August, 2015.</p> <p>Their representation was sent to pharma-trac via e-mail for confirmation / verification. Pharma-trac confirmed that their product was earlier not taken due to improper strength given by the company. The information / document submitted by M/s Neon Laboratories Ltd. & M/s Sanofi India Ltd. was not conclusive & IPDMS compliance of M/s Neon Laboratories Ltd. was also not upto 100% therefore, M/s Neon Laboratories Ltd. representation was not considered by the Authority.</p>

3.3 Company has not challenged any notification in respect of **Sodium Bicarbonate 8.4% Injection, Lignocaine-2% + Adrenaline – 1:20000 (5mcg/ml) and Adenosine 3mg/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 by the company. In reply, NPPA representatives have made no further comments.

5. Examination:

Sodium Bicarbonate Injection – 8.4%:-

The company submitted that the actual PTR of one of their products Sodac Injection is Rs.29.15/25ml., whereas NPPA has considered PTR Rs.25.00/25ml. In support of their claim, the Company has also submitted documentary proof to NPPA, copy of which is also enclosed along with review application and is available at pages 1-5/cors. In view of this, NPPA may be directed to examine the documentary proof submitted by the company about actual PTR of its product Sodac Injection, and after verification, re-fix the price of Sodium Bicarbonate Injection – 8.4%, on merit.

Lignocaine-2% + Adrenaline-1:20000 (5mcg/ml):-

The company submitted that the actual PTR of one of their products LOX 2% with Adrenaline is Rs.24.43/30ml, whereas NPPA has considered PTR Rs.22.00/30ml. In support of their claim, the Company has also submitted documentary proof to NPPA, copy of which is also enclosed along with review application and is available at pages 53-57/cors. In view of this, NPPA may be directed to examine the documentary proof submitted by the company about actual PTR of its product LOX 2% with Adrenaline, and after verification, re-fix the price of Lignocaine-2% + Adrenaline-1:20000 (5mcg/ml), on merit.

Adenosine 3mg/ml.:-

The company stated that NPPA has not included the PTR and MAT value of their formulation “ADNEON 2ML AMP” containing Adenosine 3mg/ml despite having MAT of greater than 1% market share for the period ending August, 2015. Company submitted documentary proof in support of their claim along with their review application, copy of which is placed at pages 22-38/c. NPPA stated that the representation of the company was sent to Pharmatrac for confirmation/verification. Pharmatrac confirmed that their product was earlier not taken due to improper strength given by the company. As can be seen from document placed at page 35/c, the company has submitted necessary proof giving proper strength of the formulation. In view of this, NPPA may be directed to examine the documentary proof of the company about market share of PTR and MAT value of “ADNEON 2ML AMP”, and after verification, re-fix the price of Adenosine 3mg/ml., on merit.

6. **Government Decision:**

“NPPA is hereby directed to examine the documentary proof submitted by the company about actual PTR of its product Sodac Injection, and after verification, re-fix the price of Sodium Bicarbonate Injection – 8.4%, on merit.”

“NPPA is further directed to examine the documentary proof submitted by the company about actual PTR of its product LOX 2% with Adrenaline, and after verification, re-fix the price of Lignocaine-2% + Adrenaline-1:20000 (5mcg/ml), on merit.”

“NPPA is also directed to examine the documentary proof of the company about market share of PTR and MAT value of “ADNEON 2ML AMP”, and after verification, re-fix the price of Adenosine 3mg/ml., on merit.”

Issued on this date of 28th day of September, 2016.

(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**