

**No. 31015/94/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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B Wing, Janpath Bhawan,  
New Delhi 110 001

**Subject: Review application of M/s Neon Laboratories Limited against price fixation of Adrenaline Injection - 1 mg/ml vide NPPA order No. S.O. 3181(E), dated 07.10.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Review application dated 25.10.2016**  
**2) NPPA notification under review S.O. No.3181(E) dated 07.10.2016**  
**3) Record Note of discussions held in the personal hearing held in the matter on 27.12.2016.**

1. This is a 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.3181(E) dated 07.10.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Adrenaline Injection - 1 mg/ml.

2. The petitioner has contended as under:

- I. National Pharmaceutical Pricing Authority (hereinafter referred to as NPPA) under the Department of Pharmaceutical, Ministry of Chemicals and Fertilizers, Government of India issued a notification no S.O. 3181 (E) dated 7<sup>th</sup> October, 2016, fixing prices of twenty two (22) Scheduled formulations inter alia including "VASOCON 1 MG INJECTION 1 ML" each 1ml pack containing ADRENALINE INJECTION - 1 MG/ML after giving effect of reduction in Wholesale Price Index (WPI) for the calendar year January to December, 2015.
- II. AND WHEREAS ceiling price notified for formulation ADRENALINE INJECTION - 1 MG/ML, as shared in NPPA's worksheet for S.O. **3181** (E) dated 7<sup>th</sup> October, **2016**, mentions a formulation pack under S. No. 2 namely "VASOCON 1 MG INJECTION 2 ML" and having PTR of INR. **14.10**.
- III. AND WHEREAS, Neon has never manufactured Adrenaline / Epiphrine in a 2ml pack as claimed in the worksheet.

**Under the circumstances:**

- a) NPPA has failed to accurately calculate the ceiling price of ADRENALINE INJECTION - 1 MG/ML.
- b) There was no rational for considering a fictional price of "VASOCON 1 MG INJECTION 2 ML" when such a pack size has never been manufactured or marketed.
- c) Considering "VASOCON 1 MG INJECTION 2 ML" has adversely affected the Ceiling Price and the consequently notified price is not as per the provisions of Para 4 of DPCO, 2013.

- IV. Having been aggrieved by the fact that the ceiling price of the captioned formulation ADRENALINE INJECTION - 1MG/ML was not correctly notified under S.O. 3181(E) dated 7<sup>th</sup> October, 2016 due to inclusion of an inexistant pack size as mentioned hereinabove;  
Neon files this Review Petition under Para 31 of the Drugs (Prices Control) Order, 2013 against S.O. No. 3181 (E) dated 7<sup>th</sup> October, 2016 and **request to pass a speaking order in the matter.**

The Applicant prayed as under:

1. To consider and conclude that Ceiling Price of "ADRENALINE INJECTION - 1 MG/ML" as notified vide S.O 3181 (E) dated 7<sup>th</sup> October, 2016 is incorrect and needs to be rectified within 15 days.
2. Pass a speaking order in respect hereof.
3. Any other order in interest of this manufacturer.

### **COMMENTS OF NPPA**

(i) NPPA has fixed the ceiling price Rs. 37.24 for **Adrenaline 1mg/ml Injection** vide S.O. 1565(E) dated 14.6.2013 and the same was revised to Rs. 39.59 and Rs. 41.11 for 1mg/ml injection vide S.O. 1156(E) and 619(E) dated 28.4.2014 & 26.02.2015. This was again revised to Rs. 40.00 vide S.O. 644(E) dated 02.3.2016 under NLEM 2011 of DPCO 2013.

(ii) As the product is listed in NLEM 2015 and hence in revised Scheduled – I of DPCO, 2013, NPPA fixed the ceiling price of Rs. 12.33 per pack of 1mg/ml for **Adrenaline Injection** vide S. O. 3181(E) dated 07.10.2016 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013 under NLEM 2015 based on the data provided by Pharmatrac for the month of August 2015.

(iii) DOP vide letter no. F. No. 31015/44/2016-PI.I dated 11.7.2016 gave the following, directions: "*NPPA to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceuticals firms. Only after taking into account the comments or any additional data thus received within the given time period, the NPPA shall finalize the Ceiling and the Retail Prices. This issues with the approval of Hon'ble Minister (Chemicals & Fertilizers)*". Accordingly, NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. **M/s Neon Laboratories Limited did not make any representation against the proposed ceiling price uploaded on NPPA's website.**

(iv) As regards para 4(b) of review petitions that Vasocon 1mg Injection 2ml had not been manufactured by the company, NPPA has sought clarification from Pharmatrac, reply is awaited.

3. During the personal hearing on 27.12.2016, the representative of the company shared the copy of AWACS-AIOCD certificate stating that Vasocon 1 mg injection was not available in the market in a 2 ml pack. Further, the company reiterated with a CA

certificate that they have never manufactured the mentioned pack size. A technical paper citing the usage of Adrenaline was only permitted in dosages of 1 ml also was shared by the representative of the company. Thus, the company representative requested for omission of Vasocon 1 mg injection 2 ml from the working sheet for calculation of ceiling price for Adrenaline 1 mg per ml.

NPPA representatives submitted that based on the letter received on 2.12.2016 from DoP on the issue, they have forwarded to Pharmatrac to verify about the claim of M/s Neon Laboratories Ltd. that they have never manufactured/marketed the formulation Vasocon 1 mg injection 2 ml. NPPA representatives assured to submit the verification report after receiving the confirmation from Pharmatrac.

4. **Examination:**

The company, in support of their contention that Vasocon 1 mg injection 2 ml has never been manufactured/marketed, submitted copy of AWACS-AIOCD certificate; CA certificate and a technical paper citing that the usage of Adrenaline was only permitted in dosages of 1 ml. On the request of NPPA, Pharmatrac also submitted its reply confirming that the company never manufactured/marketed 2 ml pack and is an inactive pack. The data was added due to stockiest string of this product. In view of the above, it was decided that NPPA may be directed to re-fix the ceiling price of **Andrenaline Injection – 1mg/ml**, keeping in view all the documentary proof in support of the claim of the petitioner company, on merit.

5. **Decision of the Government:**

**“NPPA is hereby directed to examine all the relevant documents/information furnished by the petitioner company and Pharmatrac, and to re-fix/revise the price of Andrenaline Injection – 1mg/ml on merit, within a 30 days of this Order and to send compliance report to the Department.”**

Issued on this date, the 5<sup>th</sup> day of April, 2017.

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

To

1. **M/s. Neon Laboratories Limited  
Dami Shamji Indl. Complex,  
M. Caves Rod, 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**