

**No. 31015/44/2017-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 "Lignocaine Topical Forms 2-5% (per gm/ml)" vide NPPA order No. S.O. 788(E), dated 10.03.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 04.04.2017.
2) NPPA notification under review S.O. No.788(E), dated 10.03.2017
3) Record Note of discussions held in the personal hearing on 17.10.2017.**

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.788(E), dated 10.03.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Lignocaine Topical Forms 2-5% (per gm/ml).

2. The petitioner has contended as under:

I. National Pharmaceutical Pricing Authority (NPPA) issued notification S.O. 788(E) dated 10th March 2017 fixing prices of Lignocaine-5% (1gm/ml) under the provisions of Para 4 of Drugs (Prices Control) Order (hereinafter referred to as DPCO), 2013.

II. AND WHEREAS, the worksheet for calculation of ceiling price of formulations notified vide S.O. 788(E) dated 10th March, 2017 erred in to aspects as mentioned below:

a. The pack size of company's Formulation namely; "LOX 5% ointment is considered as 30GM and whereas company's formulation is manufactured and marketed in a pack size of 20GM.

b. The ceiling price calculation includes both ointments and solutions whereas explanation note 1 of DPCAO, 2016 clearly states "...different dosage forms should be considered differently for purposes such as procurement policy, pricing, etc..."

III. AND WHEREAS, the price to retailer of LOX 5% as mentioned at sr. no.11 in the calculation of ceiling price is erroneously considered as Rs.18.50 for 30gm instead of Rs.18.50 for 20gm.

IV. AND WHEREAS, NPPA has further erred by considering "XYLOCAINE VISCOUS 2% SOLUTION 100ML" as mentioned at Sr. No.3 in the calculation of ceiling price along side ointments which are measured in 'grams' and not in 'ML'.

V. AND WHEREAS, Neon has fully complied with all submission requirements under IPDMS as notified by NPPA from time to time.

Under the circumstances:

- a. The Price per unit for Lox 5% (20gm pack), should be considered at Rs.0.92.
- b. The formulation namely, 'XYLOCAINE VISCOUS 2% SOLUTION 100ML' should be excluded from the pricing of ointments which are priced on per gram basis.
- c. NPPA's error would allow manufacturer of lignocaine solution to be sold at three times the MRP of lignocaine ointments that is at a ceiling price of Rs.90 Instead of 30 for a comparable pack.

VI. In view of above, company prayed as under:

- (i) To consider and conclude that Ceiling Price of "LIGNOCAINE-5% (1GM/ML)" as notified vide S.O 788(E) dated 10th March, 2017 is incorrect and needs to be rectified.
- (ii) To rectify the pack size of Lox 5% as 20GM.
- (iii) To remove the per unit rate of Xylocaine solution from the calculation of ceiling price of lignocaine ointments.
- (iv) To direct NPPA to notify the correct prices of LIGNOCAINE-5% (1GM/ML).

3. **Comments of NPPA:**

1. Ceiling price of **Lignocaine Topical Forms 2-5 %(per gm/ml)** was notified as Rs.0.97/gm or ml vide S.O. 788(E) dated 10.03.2017 and revised to Rs.0.95/gm/ml vide S.O. 2058(E) dated 30.06.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

2. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Lignocaine Topical Forms 2-5 %(per gm/ml)**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	The company stated that NPPA has erroneously considered Rs.18.50 PTR of their formulation (ROX 5% ointment) for the pack size of 30 gm against the actual pack size of 20 gm.	NPPA fixed the ceiling price Rs.0.97/gm/ml vide S.O. 788(E) based on the data provided by AIOCD-AWACS for the month of August, 2015. 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 Ltd. did not make any

		representation against the proposed retail price uploaded on NPPA's website.
2.	Company also stated that NPPA clubbed "Xylocaine viscous 2% solution 100 ml" along with ointment (available in gram) in the calculation sheet for fixing the ceiling price of subject formulation and requested to exclude Xylocaine viscous 2% solution from the pricing of subject formulation.	Lignocaine Topical forms 2-5% is included in NLEM, 2015 without differentiating between ointment and viscous solution. As decided in 27th authority meeting, all variants of the products are to be taken while calculating the ceiling price of formulation unless different variations of the formulation are specially mentioned against any formulation in NLEM, 2015 therefore NPPA considered Xylocaine viscous 2% solution 100 ml in calculation sheet for fixing Lignocaine Topical Forms 2-5 % (per gm/ml).

3. Company has not challenged any notification in respect of Lignocaine Topical Forms 2-5 % (per gm/ml) in the Court.

4. During the personal hearing, the company representatives stated that while topical forms have been mentioned as one dosage type in the first schedule of DPCO 2013, there is significant difference in the use, cost, and advantages of ointment in comparison to solution of Lignocaine 5% w/v. Therefore, the company requested to consider separate ceiling prices for solutions / ml (Avg 60 paise per ml) and ointment / mg (Avg Rs.1.1/mg) in patient interest. The company further submitted that their formulation pack size has been incorrectly mentioned in the AWACS data and they shared the formulation label claim in support of the same requesting their pack size to be considered as 20gms instead of 30gms as mentioned in the working sheet.

4.2 In response, NPPA representative stated that the ceiling price of the subject formulation was fixed as per the provisions of DPCO, 2013 based on the data available on AIOCD-AWACS/ Pharmatrac.

5. **Examination:**

The company submitted that while fixing the ceiling price of **Lignocaine Topical Forms 2-5% (per gm/ml)**, NPPA considered the PTR of one of their products, namely Lox 5% Ointment, as in a pack of 30gm, whereas the company manufacture and market in a pack size of 20gm. In support of its claim, the company submitted documentary proofs. In view of this, NPPA may be directed to examine the information/documentary proof submitted by the company in respect of pack size of its

product Lox 5% Ointment, and after verification, re-fix/revise the ceiling price of Lignocaine Topical Forms 2-5% (per gm/ml), on merit.

5.2 As regards the contention of the company about wrongly considering the PTR of “Xylocaine Viscous 2% Solution 100 ml” in calculation of ceiling price along side ointments, as ointments are measured in ‘grams’ and not in ‘ml’, it is mentioned here that Lignocaine Topical forms 2-5% is included in NLEM, 2015 without differentiating between ointment and viscous solution. Therefore, NPPA considered Xylocaine viscous 2% solution 100 ml in calculation sheet for fixing Lignocaine Topical Forms 2-5 % (per gm/ml), as all variants of the products are to be taken while calculating the ceiling price of formulation unless different variations of the formulation are specially mentioned against any formulation in NLEM, 2015. In view of this, the contention of the company has got no merit.

6. **Government Decision:**

“NPPA is hereby directed to examine the information/documentary proof submitted by the company in respect of pack size of its product ‘Lox 5% Ointment’, and after verification, re-fix/revise the ceiling price of “Lignocaine Topical Forms 2-5% (per gm/ml)”, on merit.”

“The contention of the company about wrongly considering the PTR of “Xylocaine Viscous 2% Solution 100 ml” in calculation of ceiling price along side ointments, has got no merit as all variants of the products are to be taken while calculating the ceiling price of formulation unless only specific variations of the formulation are specially mentioned against any formulation in NLEM, 2015.”

Issued on this date of 28th day of November, 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**