

**No.31015/46/2023-Pricing (E-23553)**  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

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Room No. 340-B, A Wing, Shastri Bhawan,  
New Delhi-110 001.

**Order**

M/s Neon Laboratories Limited (hereinafter called the “Applicant”) filed a Review Application dated 16.03.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 879(E) dated 24.02.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Lox Viscous 2% 100ml containing Lignocaine Hydrochloride 20mg per ml-100ml.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 06.11.2023 and presented their respective logics.

**3. Major contentions raised by the Applicant:**

It was contended, on behalf of the applicant, that NPPA has erred in determining the ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 NPPA has wrongly mentioned product name as “Lox Viscuss 2% Infusion 100ml” whereas correct name is “Lox Viscous 2% 100ml”. The formulation “Lox Viscous 2% 100ml” is a tropical/surface anesthesia having a different route of administration and dosage type to the conventional injectable. This should not have been included in the calculation of ceiling price for “Lignocaine Injection 2% per ml”. Also, the ceiling price for “Lignocaine Injection 2% per ml” should not be applicable to “Lox Viscous 2% 100ml”.

3.2 The ceiling price calculation of Lignocaine Injection 2% per ml must only include formulations having injection dosage forms containing “Lignocaine Injection 2%” and not other dosage forms containing the same strength. Therefore, NPPA has erred by including the formulation “Lox Viscous 2% 100ml” in its calculation of ceiling price for “Lignocaine Injection 2% per ml”.

**4. Gist of clarifications made by NPPA:**

NPPA on the other side argued that:

4.1 For fixing the ceiling price of the aforementioned formulation, Pharmatrac database of July, 22 was considered for calculation of ceiling prices. The product of M/s Neon Laboratories Limited appeared as “Lox Viscous 2% Infusion 100ml” in the Pharmatrac database. Therefore, the same was considered for the ceiling price calculation of Lignocaine 2% Injection.

4.2 The draft worksheet based on the Pharmatrac database was uploaded on NPPA's website on 28.01.2023 for 10 working days to invite comments, if any. M/s Neon Laboratories Ltd. vide the letter dated 7.02.2023 made representation w.r.t to their brand 'Loxicard' only and did not raise the issue of their brand 'Lox Viscous 2%' being a tropical/surface anaesthesia. In view of the above, ceiling price was fixed based on the data available in market database.

4.3 However, based on the review application, clarification was sought from Pharmatrac which confirmed that for the drug type 'Lox Viscous', the correct SKU name is "Lox viscous tropical Oral 2% Solution 100ml" and it is a "solution". Therefore, the ceiling price of Lignocaine 2% Injection needs to be revised. Further, ceiling price of Lignocaine Tropical Forms 2-5% also needs revision as now the said formulation Lox Viscous 2% shall have to be included in Lignocaine Tropical forms 2-5%.

## **5. Examination:**

5.1 Pharmatrac database of July, 2022 was considered for calculation of ceiling prices and the product of M/s Neon Laboratories Limited is appearing as "Lox Viscous 2% Infusion 100ml". Therefore, the same was considered by NPPA for the ceiling price calculation of Lignocaine 2% Injection.

5.2 Pharmatrac has confirmed that the drug 'Lox Viscous' is a "solution" and not an "Injection". Therefore, the ceiling price of Lignocaine 2% Injection needs to be revised by excluding 'Lox Viscous 2% 100ml'. Also, the ceiling price of Lignocaine Tropical Forms 2-5% would have to be revised and the formulation Lox Viscous 2% should be included for calculating the ceiling price of Lignocaine Tropical forms 2-5%.

5.3 NPPA may once again look for all such possible errors in calculation of ceiling price.

## **6. Decision:**

In the backdrop of these facts, the case is being referred back to NPPA for recalculation of ceiling prices for the subject formulation and other impacted formulation.

Issued on this, the 4<sup>th</sup> day of October, 2024.



(Awadhesh Kumar Choudhary)

Sr. Economic Adviser to the Government of India  
[For and on behalf of the President of India]

## **To:**

M/s Neon Laboratories Limited  
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Andheri (E), Mumbai-400093.

**Copy to:**

1. Chairperson, NPPA, New Delhi
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi
3. Technical Director, NIC for uploading the order on DoP's Website.
4. Guard File

