

**No.31015/69/2023-Pricing (E-23889)**  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

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Room No. 207, D Wing, Shastri Bhawan,  
New Delhi-110 001.

**Order**

M/s Sanofi India Limited (hereinafter called the "Applicant") filed a Review Application dated 28.04.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 1577(E) dated 31.03.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Clexane 20 mg injection 0.2 ml, 40 mg injection 0.4 ml, 60 mg injection 0.6 ml and 80 mg injection 0.8 ml containing Enoxaparin per 0.10 ml injection.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 25.09.2023 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 retail price of the above drug and hence may be directed to revise the retail price of their formulation on the following grounds:

3.1 M/s Sanofi India Limited is engaged in manufacturing and marketing of brands "Clexane 20 mg injection 0.2 ml, 40 mg injection 0.4 ml, 60 mg injection 0.6 ml and 80 mg injection 0.8 ml" containing "Enoxaparin per 0.10 ml". The Applicant has contended that only Enoxaparin 40 mg injection 0.4 ml and 60 mg injection 0.6 ml were included in schedule I of DPCO with effect from 11<sup>th</sup> November, 2022 but not the other strengths of Enoxaparin. NPPA issued a Notification S.O. No. 1577 (E) dated 31<sup>st</sup> March 2023, after 111<sup>th</sup> Authority meeting under the Provisions of Para 4,6,10,11,14,16,17 and 18 of DPCO, 2013, fixing ceiling prices of 127 Scheduled formulations which, inter-alia, include the Scheduled formulations manufactured by the Applicant.

3.2 The Applicant claimed that NPPA has included the formulation Enoxaparin 20 mg injection 0.2 ml, 40 mg injection 0.4 ml, 60 mg injection 0.6 ml and 80 mg injection 0.8 ml. However, a special Retail price for Enoxaparin 20 mg/0.2 ml was given vide S.O. No. 1751(E) dated 10<sup>th</sup> July, 2014 which clarifies that only Enoxaparin 40 mg and 60 mg were scheduled and not the other strengths.

3.3 Further, the Applicant has maintained that NPPA has erred by restricting the company's price to retailer in line with the Ceiling price as notified for "Enoxaparin 40 mg/0.4 ml and 60 mg/0.6 ml" to other strengths viz. 20mg / 0.2 ml, 80mg / 0.8ml of the Enoxaparin.

3.4 Also, that the calculation of Enoxaparin per 0.10 ml injection is incorrect and must be rectified after considering the company's PTR for Enoxaparin 20 mg/0.2 ml and 80 mg/0.8 ml.

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

NPPA on the other side argued that the claim of Applicant is not tenable on the following grounds:

4.1 The drug Enoxaparin is covered under different NLEMs as follows:

**NLEM, 2011:** Enoxaparin (T) Injection 40mg, Injection 60mg. Therefore, the other strengths were considered as Non-Scheduled.

**NLEM, 2015:** Enoxaparin (T) Injection 40mg/0.4ml, Injection 60 mg / 0.6ml

**NLEM, 2022:** Enoxaparin (S, T) Injection 40mg/0.4ml, Injection 60 mg / 0.6ml

4.2 Further, the contention of the petitioner that special retail price was fixed for them only in 2014 is not correct. The reasons are being that, in order to reduce the huge, inter brand variation in the prices of various companies, NPPA exercised extraordinary powers under Para 19 of DPCO 2013 in public interest and capped the prices of 84 non-scheduled cardiovascular formulations at average price of all companies +25% on 10.07.2014. Enoxaparin Injection of each 0.2 ml containing 20 mg was also covered in the notification. The price was capped based on the price of M/s Sanofi, however, subsequently these were made applicable to other companies also.

4.3 The matter of fixation of ceiling price of Enoxaparin Injection under NLEM, 2022 was deliberated in 111<sup>th</sup> meeting of Authority held on 29.03.2023. The details are as follows:

i. The ceiling price fixed under NLEM, 2015 is Rs. 112.86 per 0.1 ml for both 40mg/0.4ml and 60mg/0.6ml but notified separately.

ii. The other strengths of the Enoxaparin injection (300mg/3ml, 80mg/0.8ml, 20mg/0.2ml) are also in market with same ratio i.e. 10mg/0.1ml. Therefore, the draft working sheet was uploaded considering all the strengths with same ratio.

iii. However, representations were received stating that only ceiling prices for two packs i.e. Injection 40mg/0.4ml and 60 mg/0.6 ml may be considered as included under Schedule-I. In this context, NPPA obtained the opinion of Standing National Committee on Medicines (SNCM) and their view is as under:

*Enoxaparin sodium Injection IP 300mg/ 3ml is essentially of same strength as Injection 40 mg / 0.4 ml or Injection 60 mg/ 0.6 ml.*

*In Report of the Core-Committee for Revision of National List of Essential Medicines, 2015, it is already mentioned which is self-explanatory.*

*Page no-7 last paragraph "Any dosage form of a medicine, other than the dosage form included in NLEM, but in same strength and route of administration, which does not have*

*significant difference in terms of pharmacokinetics / pharmacodynamics / efficacy-safety profile over the dosage form mentioned in the list will be considered as included".*

*Thus, Enoxaparin Sodium Injection IP 3 ml multi-dose vial 300 mg / ml in which each ml contains Enoxaparin Sodium IP 100 mg (10,000 anti-Xa IU)" may be considered a scheduled formulation under NLEM 2015.*

## **5. Examination:**

5.1. It is observed that while NLEM 2011 included Enoxaparin (T) Injection 40mg, Injection 60mg. Thus, specific strength were included and, therefore, other strengths were considered as Non-Scheduled. However, NLEM, 2015 and NLEM, 2022 considered Enoxaparin Injection 40mg/0.4ml, Injection 60 mg/ 0.6ml. in strength per ml (i.e., mg/ml). In this context, SNCM has also opined that Enoxaparin Sodium Injection IP 300mg/ 3ml is essentially of same strength as Injection 40 mg / 0.4 ml or Injection 60 mg/ 0.6 ml and therefore, may be considered a scheduled formulation under NLEM 2015 has been noted.

5.2. Further, The Report of the Core-Committee for Revision of National List of Essential Medicines, 2015 maintains that *"Any dosage form of a medicine, other than the dosage form included in NLEM, but in same strength and route of administration, which does not have significant difference in terms of pharmacokinetics / pharmacodynamics / efficacy-safety profile over the dosage form mentioned in the list will be considered as included"* (page no-7, last paragraph, of the Report).

5.3 Taking cognizance of the recommendation of the Core Committee for Revision of National List of Essential Medicines as well as the opinion of the SNCM in this specific instance the Notification along with the clarification is found to be in order.

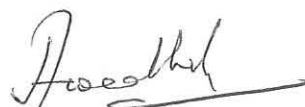
## **6. Conclusion**

Through the detailed examination noted above, it is observed that, NPPA has appropriately fixed the ceiling prices for Enoxaparin Injection 40mg / 0.4ml and 60 mg / 0.6 ml and made them applicable to any other strengths (such as 300mg / 3ml, 80mg / 0.8ml, 20mg / 0.2ml etc.) of the Enoxaparin with same ratio i.e. 10mg / 0.1ml).

## **7. Decision**

The action of NPPA fixing the ceiling prices of Clexane 20 mg injection 0.2 ml, 40 mg injection 0.4 ml, 60 mg injection 0.6 ml and 80 mg injection 0.8 ml containing Enoxaparin per 0.10 ml injection vide SO no. 1577(E) dated 31.03.2023 is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 8<sup>th</sup> day of February, 2024.



**(Awadhesh Kumar Choudhary)**

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

**To:**

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**Copy to:**

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