

**No. 31015/19/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

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**A- Wing, Shastri Bhawan,
New Delhi 110 001**

Subject: Review application of M/s Sanofi India Limited against price fixation of "Furosemide Injection (Furosemide-10mg/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 14.03.2017
2) NPPA notification under review S.O. 788(E), dated 10.03.2017
3) Record Note of discussions held in the personal hearing held in the matter on 9.5.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sanofi India 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 Furosemide Injection (Furosemide-10mg/ml)

2. The petitioner has contended as under:-

- I. Considering that there was an apparent error in the Draft Version of Proposed Price Calculation Sheet for proposed ceiling price of Rs. 1.01 per ml. in respect of Furosemide Injection (Furosemide-10mg/ml displayed on NPPA website which was uploaded on 21st February, 2017, they made a detailed representation to NPPA vide their letter dated 3-3-2017 pointing out errors in working out the proposed ceiling price by including prices of non-existent products.
- II. Since the price fixation of Furosemide Injection (Furosemide-10mg/ml) is not in consonance with the relevant provisions of the DPCO 2013 and being aggrieved by such price fixation/ notification vide SO 788 (E) dated 10th March 2017 issued under Para 4,6,10,11,14,16,17 and 18 of DPCO 2013, we file review application under Para 31 of the said DPCO within the prescribed limit of 30 days of date of publication of the notification in respect of our above mentioned formulation on the following grounds:
 - (i) NLEM/Schedule I of DPCO 2013, includes in Section 18.1 the following entry :
Frusemide Injection 10mg /ml
 - (ii) In the working sheet, there are four packs of Sanofi shown as given below:

S N o	Pack Description	Pack Size and Unit	PTR (Rs)	MAT (Rs)	SKU-Wise MAT %	Company Levelwise MAT	Qualify (Y/N)	Price per unit considered
1	Lasix 10 mg Injection 2ml	2 ml	1.95	130,15,075	15.91%	100%	Y	0.98
2	Lasix HD 10 mg Injections 5ml	5 ml	2.46	9,191	0.01%	100%	Y	0.49
3	Lasix 20 mg Injection 2 ml	2 ml	2.69	669,39,879	81.81%	100%	Y	1.35
4	Lasix 250 mg Injection 25 ml	25 ml	19.48	18,59,110	2.27%	100%	Y	0.78

There are errors in Serial Number 1, 2 and 4 and they gave their comments against the respective items

Sr No	Pack Description	Comments
1	Lasix 10 mg Injection 2ml	We do not manufacture Lasix 10 mg in 2ml. Lasix 2ml contains Frusemide 10mg per ml (i.e. 20 mg per 2ml pack)(see Manufacturing License)
2	Lasix HD 10 mg Injections 5ml	We do not manufacture or sell this product
3	Lasix 20 mg Injection 2 ml	PTR Rs 1.35 is okay
4	Lasix 250 mg Injection 25 ml	We do not manufacture or sell this product

- (iii) They confirmed that in August 2015 they were manufacturing and selling only one pack of Frusemide Injection 10mg/ml namely Lasix 2ml (containing Frusemide 10mg/ml i.e. 20mg in 2ml) which is listed in Sr. No 3 above.
- (iv) Thus there is only one formulation pack Lasix Injection 2ml containing Frusemide 10mg/ml (or 20 mg in 2ml) and the average price for the Frusemide 10 mg/ml will be same as the existing price of Lasix 2 ml pack mentioned in serial number 3 above.
- (v) **They further submitted that as Frusemide was a scheduled formulation even under DPCO, 1995, as provided in para 6(2) of DPCO, 2013, no price reduction using monopoly factor is permissible, while fixing the ceiling price.**
- (vi) Vide S.O. 2360 dated 15.9.2014, NPPA had fixed a very low ceiling price of Rs. 1.13 per ml by wrongly applying para 6 for this product. They had implemented this price in compliance with DPCO before filing a Review Application. Subsequently following a Review Petition filed by them, the ceiling price of Frusemide 10 mg/ml was fixed vide S.O.1204 (E) dated 6th May 2015 at Rs 1.58 per ml
- (vii) The average PTR considered while fixing this ceiling price was Rs 1.36 per ml. It may be noted that $1.36 + 16\% \text{ of } 1.36 = \text{Ceiling Price Rs } 1.58 \text{ per ml}$

(viii) MRP for Lasix 2ml (Frusemide 10 mg/ml) was fixed as follows

MRP for 1 ampoule = (1.58 + VAT 5%)* 2 = Rs 3.31

MRP for 10 ampoules = 3.31* 10 = Rs 33.10

The above price was prevalent in August 2015 (see Invoice dated 17th August 2015, which shows Lasix 10 X 2 ml MRP is Rs 33.10 and PTR Rs 27.17 per 10 ampoules of 2 ml each)

(ix) Lower PTR reflected in the average price due to incorrect price notified by S.O. 2360 dated 15.9.2014 should be ignored while fixing the price now.

(x) **They attached the letter dated 28th February, 2017 received from AIOCD AWACS that the correct PTR of Lasix 2ml for August 2015 is Rs 2.69 and that it constitutes 100% Market Share in Frusemide 10mg/ml Injection**

(xi) It is also pertinent to note the following facts:-

Frusemide was a Scheduled formulation even under DPCO, 1995 and its selling price was fixed by NPPA at Rs 2.81 per ampoule vide SO 434 dated 29th March 2006 and had remained constant till notification of DPCO 2013. Thereafter there were marginal increases/decreases due to WPI changes. Due to very low prices the Company has suffered a huge loss in Lasix 2 ml. They summarised the Sales and Profit/ (Loss) as per Cost records

Rs (Million)	2013	2014	2015	Total
Lasix Injection				
Sales	66	74	72	212
Profit /(Loss)	(20)	(26)	(41)	(87)

Due to very low prices, no other manufacturer has shown any interest to manufacture this product and they have an unenviable monopoly in this unviable product. Sanofi India Limited has been manufacturing this product in public interest in spite of incurring such losses.

(xii) We had applied to NPPA for upward revision of prices to Rs 2.70 per ml in June 2016, which is under the consideration of NPPA.

(xiii) They will re-iterate that any reduction in ceiling price from current level will severely affect the viability forcing us to take steps for discontinuation in accordance with provisions of para 21.

III. In view of the position as explained above, there is no justification for price fixation of Furosemide Injection (Furosemide-10mg/ml) in the manner as adopted by the NPPA which is against the provisions of the DPCO 2013. It is, therefore, requested that the ceiling price of Furosemide Injection (Furosemide-10mg/ml) notified vide S.O. 788 (E) dated 10th March 2017 may be withdrawn immediately.

3. **Comments of NPPA:**

NPPA has fixed the ceiling price based on the data provided by pharmanac for the month of August 2015. Company has not provided the information/document required as per OM no 8(34)/2016/Div.II/DP/NPPA dated 10.10.2016. Further, earlier representation of the company was not considered by NPPA as the company had not complied with IPDMS up to 100% (at that time).

4. **Examination:**

The petitioner company has challenged the NPPA Order S.O. 788(E), dated 10.03.2017 for price fixation of their formulation **Furosemide Injection (Furosemide-10mg/ml)** on the ground that NPPA has erred by considering their four formulations, namely Lasix 10mg Injection 2ml, Lasix HD 10mg Injection 5ml, Lasix 20mg Injection 2ml & Lasix 250mg Injection 25ml to derive the average PTR for this formulation while **company has been manufacturing and marketing only one pack of Furosemide Injection 10mg/ml namely Lasix 2ml (containing Furosemide 10mg/ml).**

In this connection, NPPA has stated that the ceiling price of the formulation has been fixed based on the data provided by pharmanac for the month of August 2015. Further, earlier representation of the company was not considered by NPPA as the company had not complied with IPDMS up to 100% (at that time).

On examination, it is found that the company has filed documentary proof in support of their claim that the company is manufacturing only Lasix 20 mg injection 2 ml and the other three products are not in production. The company has also submitted necessary information/documents in proper forms vide their letter, dated 22.3.2017 to NPPA.

In view of the above, it is decided that NPPA may be directed to examine all the relevant documents/information furnished by the petitioner company, get confirmation from Pharmanac about the authenticity of the claim of the petitioner company and re-fix the ceiling price of Furosemide Injection (Furosemide-10mg/ml), on merit.

5. **Government Decision:**

“NPPA is hereby directed to examine all the relevant documents/information furnished by the petitioner company and re-fix the ceiling price of Furosemide Injection (Furosemide-10mg/ml), on merit, within 30 days of this Order and to send the compliance report to the Department.”

Issued on this date, the 24th day of August, 2017.

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

To

1. M/s. Sanofi India Limited
Sanofi House, CTS No.117-B,
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Saki Vihar Road,
Powai, Mumbai-400 072.
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