

**No. 31015/23/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

B Wing, Janpath Bhawan,  
New Delhi 110 001

**Subject:** Review application of M/s Lupin Ltd. against price fixation of Levofloxacin 500 mg vide NPPA order No. S.O. 1253(E) dated 29.03.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013) and NPPA's work sheet 02.04.2016.

**Ref:** 1) Review application dated 02.05.2016  
2) NPPA notification under review S.O. No.1253(E) dated 29.03.2016 and NPPA work sheet dated 02.04.2016.  
3) Record Note of discussions held in the personal hearing held in the matter on 8.6.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Lupin Ltd. (hereinafter called the petitioner) against notification S.O. No.1253(E) dated 29.03.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) and work sheet placed on NPPA web site on 2.4.2016 fixing the ceiling price of Levofloxacin 500 mg.

2. The petitioner has contended as under:

- i. Company referred price notification S.O. 1253(E) dated 29<sup>th</sup> March 2016 and the work sheet put up on the NPPA web site on 2<sup>nd</sup> April 2016 in connection with the **Incorrect Ceiling Price Notified Due to Discrepancy in PTR for Levofloxacin 500 MG**. They referred to the work-sheet available on NPPA web site relating to calculation of PTR for Levofloxacin 500 MG Tablet.
- ii. Company further submitted that the PTR considered for Levoday & Levocad of Zydus Cadila seems to have been taken erroneously, because PTR as reflected in IMS data for the August 2015 shows details as given below.

SKU	Company	PTR	Remarks
Levoday 500 mg (ST)	Zydus Cadila	8.27	Price in NPPA circular is 4.14/tab. 0.28/T
LEVOCAD 500mg (10 T)		5.90	

Applying the correct PTR for Zydus Cadila's Pack of Rs. 8.27 & 5.90 the revised PTR works out as under:

Sum of MAT value considered for price calculation	:	121.38
Less: incorrect Levoday & Levocad PTR	:	(4.14) + (0.28)
Add: correct value of Levoday & Levocad PTR	:	8.27 + 5.90
New revised MAT value for price Calculation	:	131.13

Number of Packs considered	:	22
Average PTR	:	5.96
Add: retail margin @16%	:	0.95
Ceiling Price without Local Taxes	:	6.91

### **Comments of NPPA:**

- i. Company request for correcting ceiling price due to discrepancy in PTR for Levofloxacin 500 mg tablet is under consideration and letter has been issued by this office to M/s Zydus Cadila Healthcare Ltd. requesting for actual PTR and MAT value for Levoday 500mg and Levocad 500mg as per OM No. F. No. 19(714)/2016/Div. II/DP/NPPA dated 20/05/2016.
- i. Necessary action in this regard will be taken by this office after examination of the case and approval of the Authority.

3. In the personal hearing held on 8.6.2016, the company representative stated that they have nothing more to submit in addition to their written submission.

The NPPA representative stated that they have written a letter to M/s Zydus Cadila Healthcare Ltd. requesting for actual PTR and MAT value for Levoday 500mg and Levocad 500mg as per OM No. F. No. 19(714)/2016/Div.II/DP/NPPA dated 20/05/2016. On receipt of information from M/s Zydus Cadila Healthcare Ltd., necessary action, in this regard, will be taken by NPPA after examination of the case and approval of the Authority. However, M/s Lupin has intimated to NPPA that to consider the PTR of Levocad for this pack is irrelevant as the pack does not contain Levofloxacin.

### **4. Examination:**

On examination, it is found that NPPA has erred in calculating ceiling price as per para 4 of DPCO, 2013, which reads as under :-

#### ***“4. Calculation of ceiling price of a scheduled formulation***

*(1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the First Schedule shall be calculated as under:-*

**Step 1:** *First the Average price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:-*

**Average Price to Retail P(s) =** *(Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine)/(Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine).”*

It clearly mentions the medicines which are to be taken for calculation. In the instant case, the principles applied by NPPA go beyond what is mentioned in DPCO. Hence, NPPA may be directed to refix the ceiling price in accordance with the provisions of DPCO. The DPCO does not recognise a company for average PTR but only medicines / formulations. Thus, only 12 formulations are to be considered having MAT value of more than 1% each instead of 22 considered by NPPA in its calculation.

NPPA is also directed to consider the actual PTR and MAT value for Levoday 500 mg.

4. **Decision of the Government:**

The ceiling price fixation of Levoflexacin 500 mg by NPPA, vide S.O.No.1253(E), dated 29.03.2016, in deviation of DPCO, 2013, is hereby quashed and the NPPA is directed to refix the ceiling price in accordance with the provisions of DPCO by considering the PTR of 12 formulations only. The DPCO does not recognise a company for average PTR but only medicines / formulations. NPPA is further directed to consider the actual PTR and MAT value for Levoday 500 mg.

Issued on this date, the 6<sup>th</sup> day of October, 2016.

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

To

1. M/s. Lupin Ltd.  
C/4, Laxmi Towers, Bandra Kurla Complex,  
Bandra (East), Mumbai-400 051.
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