

No. 31015/21/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: Review application of M/s Mankind Pharma Limited against price fixation of Phynal-500 (Livofloxacin Tablet) vide NPPA order No. S.O. 1253(E) dated 29/03/2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 02.05.2016
2) NPPA notification under review S.O. No.1253(E) dated 29.3.2016
3) Record Note of discussions held in the personal hearing held in the matter on 16.6.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Mankind Pharma Limited (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) fixing the ceiling price of Phynal-500 (Livofloxacin Tablet).

2. The petitioner has contended as under:

- (i) In exercise of the powers, conferred by paragraph 4, 10, 11, 14, 16 and 17 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the ceiling prices as specified in column (5) with immediate effect and revised ceiling prices as column (6) of the table herein below, exclusive of local tax applicable, if any, in respect of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

Sr. No.	Name of Schedule Formulation	Strength	Unit	Ceiling Price (Rs.)	Revised Ceiling Price (Rs.) including WPI w.e.f 1.4.2016
(1)	(2)	(3)	(4)	(5)	(6)
36	Levofloxacin Tablets	Levofloxacin500 Mg	1 Tablet	6.40	6.23

- (ii) The grounds for their review application are as follows:
- (a) As per working sheet uploaded on NPPA's website dated 02/04/2016 the Pack Size of their product FYNAL-500 TABLET (Levofloxacin Tablet) at S.No. 62 is mentioned as 10 tablets whereas their pack size is 5 Tablets which is also mentioned at S. No. 64 on aforesaid worksheet. **While PTR is considered the same in both the cases as applicable in case of the pack of 5 Tablets.**
 - (b) PTR is considered on the basis of MRP Rs. 36.85 existing at that time for pack size of 5 Tablets.

In view of the above grounds, the petitioner company submitted that the **PTR of aforesaid products with pack size of 10 Tablets mentioned at S. No. 62 is incorrect and should not be considered while calculating the ceiling price.** They further submitted that, however, they have already implemented the ceiling price as issued vide above notification. They requested this Department to revalidate the data in case of Levofloxacin -500 mg Tablet and issue the ceiling price accordingly.

3. The contentions of petitioner and the NPPA were heard on 16th June, 2016. During the hearing, the petitioner company did not submit any more submission. NPPA representative requested the hearing authority to direct the company to submit the documents / information as per OM F.No.19(714)/2016/Div.II/DP/NPPA, dated 20th May, 2016, which states that ***“all the companies aggrieved by NPPA's price fixation may make representations, if any, against the ceiling prices fixed by the NPPA, by submitting documents / information of Price to Retailer (PTR) and Moving Annual Turnover (MAT) data along with supporting documents like copies of invoices to retailer and samples of August, 2015 duly self-attested with name, designation, mobile no., signature & seal of the authorised officer of the company, within 15 days of the price notification in order to enable NPPA to take necessary action in this regard.”*** The petitioner company representatives agreed to submit the required documents/information accordingly.

The NPPA representative stated that on receipt of the information, the same will be examined by NPPA and may be put up in the Authority Meeting of the NPPA.

4. **Decision of the Government:**

NPPA is directed to re-fix the ceiling price of “Fynal-500 (Levofloxacin Tablet)” after taking into consideration data furnished by the petitioner company on merit within a period of one month from the date of issue of this Order.

Issued on this date, the 22nd day of July , 2016.

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

To

- 1. M/s. Mankind Pharma Ltd.,
208, Okhla Industrial Estate, Phase-3,
New Delhi-110 020.**
- 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**