

**No. 31015/35/2017-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 Blue Cross Laboratories Pvt. Limited against price fixation of "Mefenamic Acid - Tablets 250mg and 500mg" vide NPPA order No. S.O. 4127(E), dated 22.12.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 18.01.2017
2) NPPA notification under review S.O. 4127(E), dated 22.12.2016
3) Record Note of discussions held in the personal hearing held in the matter on 06.06.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Blue Cross Laboratories Pvt. Limited (hereinafter called the petitioner) against notification S.O. No.4127(E), dated 22.12.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Mefenamic Acid - Tablets 250mg and 500mg.

2. The petitioner has contended as under:-

- I. The above formulations were introduced for the first time in the revised NLEM 2015.
- II. NPPA displayed the Proposed Price Calculation Sheet for Mefenamic Acid – Tablet-250 mg and 500 mg. vide Office Memorandum No. 8(35)/2016/DP/NPPA/Div.II dated 26.10.2016 on its Website.
- III. The fixation of the ceiling prices of Mefenamic Acid – Tablet -250 mg and 500 mg have not been exercised in accordance with the letter and spirit of the DPCO 2013 particularly terms of the provisions of paragraphs 4 and 16 of the DPCO 2013.
- IV. The appellant Company made representation to NPPA with a request to work out the ceiling price for both the products without applying the reduction of 2.71% on account of WPI 2015.
- V. NPPA notified S.O. 4127(E) on 22nd December, 2016 In exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, to fix the ceiling prices, without taking into consideration of the representation made by the Appellant Company, as below:

S. No.	Name of the Scheduled Formulation	Strength	Unit	Ceiling Price (Rs.)
1.	Mefenamic acid Tablet	Mefenamic acid-500mg	1 Tablet	2.27
2.	Mefenamic acid Tablet	Mefenamic acid-250mg	1 Tablet	1.78

- VI. The appellant Company has implemented the ceiling prices as notified by the aforesaid price fixation Notifications dated 22nd December, 2017 and has intimated NPPA through IPDMS and the State FDA's accordingly. The appellant Company shall not sell the above scheduled formulations at a price exceeding the ceiling price fixed by the Government of which a review has been applied for.
- VII. NPPA is yet to act on the rectification of the errors that have crept in while fixing the ceiling prices of the above formulations.
- VIII. Being aggrieved by the said Notification No. S.O. 4127(E) issued on 22nd December, 2016, the appellant prefers to present 1st appeal.

G R O U N D S O F A P P E A L

- On the facts and the circumstances of the case explained above NPPA is not justified in notifying the Ceiling prices of the products in question without taking into consideration the representation of the appellant Company.
- NPPA is not justified in applying the WPI reduction by 2.7105%, which is unfair and contrary to the provisions of the DPCO 2013.
- It is apparent that the aforesaid Notification has been issued for "fixing" for the first time the Ceiling Prices in respect of the formulations mentioned therein, which includes our subject formulations, in view of their inclusion in the revised NLEM 2015.
- The applicability of Para 16 is appropriate only in the cases where there is revision of prices. However, there is no revision involved in fixing the ceiling price of product that has become scheduled drug for the first time. Since it is a case of fixation of price of a formulation that has become scheduled for the first time, the concept of applicability of WPI does not seem to be correct.
- Since the Ceiling price is fixed in respect of the subject formulation for the first time, the concept of "revision" cannot apply and consequently the provisions of paragraphs 16 & 18, both of which deal with "revision" cannot be attracted and the question of applying any effect of the WPI change does not arise. Hence, applying WPI without the ceiling price having been fixed is not in accordance with the provisions of DPCO 2013.
- In view of the above, NPPA has erred in applying WPI in this case where it is not applicable.
- The Department of Pharmaceuticals has already decided on 6th October, 2016 while disposing off the review petition of M/s Alkem Laboratories Ltd. against price fixation of "Cefotaxime 1 gm injection", The molecule which was introduced

for the first time in the revised NLEM 2015, vide NPPA order No. S.O. 1817(E) dated 18.05.2016 and S.O. 1405(E), dated 12.4.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

The Government has decided as below:

“NPPA is hereby directed to re-fix and re-notify the price of the products of the petitioner company under Para 4, by taking the correct data, taking into account Para 9(5) of DPCO, 2013, and without applying WPI change in ascertaining the ceiling price. The same principles should be applied to all other such cases also by NPPA.”

P R A Y E R

The appellant Company, therefore, prays that-

NPPA to be directed to re-fix and re-notify the Ceiling price of the products of the petitioner company under Para 4, without applying WPI change in ascertaining the ceiling price.

3. Comments of NPPA:

- i. In this regard, it is mentioned that ceiling price of Rs. 1.78/Tablet for **Mefenamic Acid 250mg and Rs. 2.27/tablet for Mefenamic Acid 500mg** was notified vide S.O. 4127(E) dated 22.12.2016 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.
- ii. Company has stated that correct methodology was not followed in arriving at the ceiling price for **Mefenamic Acid 250mg and 500mg**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

iii.

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has pointed out that they have made representation by e-mail within 10 working days against O.M. No. 8(35)/2016/DP /NPPA/ Div.II dated 26.10.2016 in line with para 4 and 16 of DPCO, 2013. NPPA did not consider the representation. Company has challenged the application of negative WPI @ -2.7105 in ascertaining of ceiling price for this formulation. Company has also submitted copy of review order no. 31015/43/2016-PI.I	NPPA examined the representation submitted by the company but the representations was not considered on the following grounds:- (a) NPPA has been consistency applying the effect of WPI fixation of ceiling price of all schedule formulation under NLEM 2015. Non-applicability of WPI in calculation of ceiling price based on the review order would be applicable only on the formulation for which the review petition has been filed on which the review order has been given NPPA has fixed the ceiling price with reference to SO 701(E) dated 10.03.2016 and WPI

	dated 06.10.2016 in support of their claim.	under para 16(1) is mandatory. There is no condition in the DPCO 2013 that only single provision of 9(5) or 16(1) to be applied and both the above provisions are mandatory. DOP in order no. 31015/13/2014-PI.I dated 16/07/2014 and 31015/33/2014 dated 23/07/2014 supported the stand taken by NPPA regarding application of WPI in price fixation exercise. Therefore the representation given by M/s Blue Cross was not considered by NPPA.
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iv. Company has not challenged any notification in respect of **Mefenamic Acid 250mg and 500mg** in the Court.

4. During the personal hearing, the representatives of the company made the following submissions in addition to the written submission already submitted –

1. The applicability of Para 16 is appropriate only in the cases where there is revision or prices.

Para 16(1) of DPCO, 2013 reads as under:

“The Government shall revise the ceiling prices of scheduled formulations as per the annual Wholesale Price Index (WPI) for preceding year on or before 1st April of every year and notify the same on the 1st day of April every year.”

However, there is no revision involved in fixing the ceiling of product that has become scheduled drug for the first time. Since, it is a case of fixation of price of a formulation that has become scheduled for the first time, the concept of applicability of WPI does not seem to be correct.

2. NPPA should have fixed the ceiling price of the product taking into account the data available for the month ending immediately before six months of the Notification of revision in the first schedule i.e. 10.03.2016 in the instant case in terms of Para 9(5) of the DPCO, 2013.

Para 9(5) reads as under:

“The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six months of notification of revision in the first schedule.”

Accordingly, NPPA has erred in applying WPI in this case where it is not applicable.

The company representatives prayed that NPPA to be directed to re-fix and re-notify the ceiling price of the product of the petitioner company under Para 4 without applying WPI change in ascertaining the ceiling price.

The NPPA representatives submitted that the ceiling price of **Mefenamic Acid – Tablets 250 mg and 500 mg.** has been fixed based on the policy decision taken by the Authority.

5. Examination:

In the instant case, the company's contention is that application of negative WPI @ -2.7105 while fixation of ceiling price of the formulations **Mefenamic Acid - Tablets 250mg and 500mg.** is not in accordance with the provisions of DPCO, 2013.

5.2 In this regard, it is submitted that para 9(5) of DPCO, 2013 reads as under:

“The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six months of notification of revision in the first schedule.”

5.3 In this case, the products Mefenamic Acid – Tablet-250mg and 500mg **have become scheduled formulations vide DoP's SO 701(E), dated 10.3.2016. As per para 9(5) of DPCO, 2013, while fixing the ceiling price, the data to be considered is of six months prior to notification, i.e. August, 2015 in this case. Hence the WPI factor will apply in the instant case.**

5.4 In view of the above, the hearing authority is of the opinion that NPPA has fixed the ceiling prices of Mefenamic Acid – Tablet-250mg and 500mg as per para 9(5) of DPCO, 2013 and factoring WPI is in order, as the base data is of August, 2015. Hence, the grievance of the petitioner company has got no merit and may be rejected.

6. Government Decision:

“NPPA has fixed the ceiling prices of Mefenamic Acid – Tablet-250mg and 500mg as per para 9(5) of DPCO, 2013 and factoring WPI is in order, as the base data is of August, 2015. Hence, the grievance of the petitioner company has got no merit and stands rejected.”

Issued on this date, the 11th day of December, 2017.

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

To

1. M/s Blue Cross Laboratories Pvt. Limited,
Nasik Plant: A-12, Ambad Industrial Area,
Nashik-422 010.
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