

No. 31015/55/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A- Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Two Review applications of M/s J.B. Chemicals & Pharmaceuticals Limited against price fixation of “Metronidazole Oral Liquid 200mg/5ml and Metronidazole 500mg/100ml” vide NPPA order No. S.O. 1039(E), dated 01.04.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review applications dated 19.04.2017 and 20.4.2017.
2) NPPA notification under review S.O. 1039(E), dated 01.04.2017
3) Record Note of discussions held in the personal hearing held in the matter on 11.07.2017.

1. These are the two petitions under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s J.B. Chemicals & Pharmaceuticals Ltd. (hereinafter called the petitioner) against notification S.O. No.1039(E), dated 01.04.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Metronidazole Oral Liquid 200mg/5ml and Metronidazole 500mg/100ml.

2. The petitioner has contended as under:-

I. National Pharmaceutical Pricing Authority (NPPA) issued notification no S.O. 1039 (E) dated 01st April, 2017 revising prices by WPI of calendar year 2016 of Metronidazole IV – 500mg/100ml at Sr. No. 438 and Metronidazole oral liquid 200mg /5 ml at Sr. No. 439 under the provisions of Para 4 and 6 of Drugs (Prices Control) Order (DPCO), 2013.

II. **In respect of METRONIDAZOLE - 500MG/100ML**

(i) AND WHEREAS, the base ceiling price for METRONIDAZOLE IV 500mg/100ml was inaccurately notified vide S.O. 443(E) dated 14TH February, 2017 wherein NPPA had erred by considering the incorrect ceiling price of our formulation and the company had subsequently filed review petition with the Department of Pharmaceuticals on 16TH Feb'2017.

(ii) AND WHEREAS, the date of personal hearing has not yet been granted by DOP and the price must be considered under review.

Under the circumstances:

(a) NPPA had erred in accurately notifying the ceiling price of Metronidazole IV – 500mg/100ml vide S.O. 443 (E) dated 14TH February, 2017.

- (b) NPPA must first either correct the base ceiling price in accordance with PARA 4 of DPCO 2013 or wait for the DoP review order before renotifying the ceiling price of Metronidazole IV – 500mg/100ml.
- (c) Having been aggrieved by the fact that the captioned formulation was inaccurately priced and yet NPPA has once again committed an error of principal and to maintain equity of justice, NPPA must be directed to consider and allow the WPI increase after review of S.O 443(E) dated 14th February, 2017 if deemed to be erroneous by DoP.

III. In respect of METRONIDAZOLE Oral Liquid 200mg/5ml

- (i) AND WHEREAS, the base ceiling price for Metronidazole Oral Liquid inaccurately notified vide SO. 3182(E) dated 7th Oct, 2016 wherein NPPA had erred by considering the incorrect ceiling price of their formulation.

Under the circumstances:

- a. NPPA had erred inaccurately notified the ceiling price of Metronidazole Oral Liquid as per the provision of Para 4 vide S.O. No.1561(E) dated 27th April 2016.
- b. NPPA is now compounding the same error by revising the ceiling price to effect of WPI of the calendar year 2016(1.97186%).
- c. NPPA must first either correct the base ceiling price in accordance with Para 4 of DPCO 2013 or wait for Review petition order.

IV. In view of above, applicant prayed as under:-

- a. To consider and conclude that NPPA had erred in pricing of their formulation Metronidazole IV – 500mg/100ml vide S.O. 443(E) dated 14TH February, 2017 and again vide S.O 1039 (E) dated 1st April, 2017.
- b. To consider and conclude that NPPA had erred in pricing of our formulation Metronidazole Oral Liquid under Notification no. S.O. 3182(E) dated 07th October, 2016.
- c. To consider and conclude that NPPA must revise the ceiling price of the Metronidazole Oral Liquid in accordance with provisions of Para 4 of DPCO, 2013 considering all SKUs having market share more than 1%
- d. Pass a speaking order in respect hereof.
- e. Any other order in interest of this manufacturer.

3. **Comments of NPPA:**

- I. Ceiling price Rs. 0.25/ml vide SO 1561(E) dated 24.04.2016 and the same was revised to Rs. 0.27/ml in terms of the decision taken in its 37th meeting held on 06.10.2016 vide S.O. No. 3182(E) dated 07.10.2016 considering the representation of companies. The ceiling price of subject formulation was again revised to Rs. 0.28/ml vide SO 1039(E) dated 01.04.2017. and ceiling price for **Metronidazole 500mg/100ml Injection** was notified as Rs. 0.12039/ml vide S.O. 443(E) dated 14.02.2017 and revised to Rs. 0.12276/ml vide S.O. 1039(E) dated 01.04.2017 as per para 4, 10, 11, 14, 16, 17 & 18 under DPCO 2013.
- II. The company stated that correct methodology was not followed in arriving at the ceiling price for **Metronidazole Oral Liquid 200mg/5ml and Metronidazole 500mg/100ml Injection**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013 and as per the decisions of 41st Authority meeting held on 13.02.2017. Details are as follows:-

S. No.	Company's Grievances	NPPA's comments
1. (i)	<p><u>Metronidazole Oral Liquid 200mg/5ml:-</u></p> <p>A. The company stated that NPPA had inaccurately notified the ceiling price of Metronidazole Oral Liquid as per the provision of para 4 vide SO no. 1561(E) dated 27.04.2016.</p> <p>B. NPPA is now compounding the same error by revising the ceiling price to effect of WPI of the calendar year 2016 (1.97186%)</p> <p>C. NPPA must either correct the ceiling price in accordance with para 4 of DPCO, 2013 or wait for review petition order.</p>	<p>NPPA fixed the ceiling price Rs. 0.25/ml vide SO 1561(E) dated 24.04.2016 (subsequently changed as 1560(E) and the same was revised to Rs. 0.27/ml in terms of the decision taken in its 37th meeting held on 06.10.2016 vide S.O. No. 3182(E) dated 07.10.2016 considering the representation of companies. The ceiling price of subject formulation was again revised to Rs. 0.28/ml vide SO 1039(E) dated 01.04.2017. The S.O. 1039(E) dated 01.04.2017 was issued to give the effect of WPI applicable from 01.04.2017 only.</p> <p>NPPA has been fixing the ceiling price of scheduled formulation in accordance with the provisions of para 4 of DPCO, 2013. This policy has been followed by NPPA consistently.</p>
(ii)	Having being aggrieved by the errors in calculation of ceiling price, company filed review petition under para 31 of DPCO, 2013 against SO 3182(E) dated 07.10.2016. Company has also requested that NPPA must	Review order is awaited. Company filed a second review application without awaiting for order in respect of its first review application. This is not correct as per DPCO, 2013.

	revise the ceiling price of Metronidazole Oral Liquid in accordance with provision of para 4 of DPCO, 2013 considering all SKUs having market share more than 1%.	
2.	<p><u>Metronidazole 500mg/100ml Infusion</u></p> <p>a. The company stated that NPPA had erred inaccurately notifying the ceiling price of Metronidazole IV - 500mg/100ml Injection vide SO 443(E) dated 14.02.2017.</p> <p>b. NPPA must first correct the base ceiling price in accordance with para 4 of DPCO, 2013 or wait for the DOP review order before re-notifying the ceiling price of Metronidazole IV - 500mg/100ml Injection.</p> <p>c. NPPA must be directed to consider and allow the WPI increase after review of 443(E) dated 14.02.2017 if deemed to be erroneous by DOP.</p> <p>d. NPPA had erred in pricing of Metronidazole IV - 500mg/100ml Injection vide SO 443(E) dated 14.02.2017 and again SO 1039(E) dated 01.04.2017.</p>	<p>NPPA has fixed ceiling price Rs. 0.12039/ml in terms of decision taken in 41st meeting held on 13.02.2017 vide SO no. 443(E) dated 14.02.2017.</p> <p>NPPA has been following this practice consistently since 10.03.2016 in the fixation of ceiling price of all scheduled formulations included in revised schedule-I of DPCO, 2013.</p> <p>NPPA fixed the ceiling price Rs. 0.12039/ml vide S.O. 443(E) dated 14.02.2017 under NLEM 2015 considering para 18(1) of DPCO, 2013. The S.O. 1039(E) dated 01.04.2017 was issued to give the effect of WPI applicable from 01.04.2017 only.</p>
2.	Company has also pointed out that NPPA should wait DOP's review order filed by the company against SO 443(E) dated 14.02.2017 in respect of Metronidazole 500mg/100ml Injection and allow the WPI increase after review of SO 443(E) dated 14.02.2017.	
		<p>Detail of trade margin based on AIOCD-AWACS data as on August 2015:-</p> <p>Trade Margin from PTS level of the product of J.B. Pharmaceuticals.:- Metronidazole IV 500mg Infussion 100ml Injection – 47.3% Metronidazole Oral Liquid 200mg/5ml:-</p>

		Metronidazole Oral Liquid 200mg/5ml – 30ml – 25.53% Metronidazole Oral Liquid 200mg/5ml – 60ml – 25.59%
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4. During the personal hearing the representative of the company submitted that that NPPA had erred by notifying under Para 4 considering the prices prevalent in Aug'2015 inspite of having superseded the price of SO 3023 (E) dt. 9th Nov'2016. The company representative also stated that their case is Identical to the Review applications of M/s Abbott Healthcare Pvt. Limited against price fixation of their formulations Phenobarbitone 30 mg which stated as under:

“The petitioner company challenged the price calculation for Phenobarbitone 30 mg against SO 28.6.2013 and SO 1785(E) dated 10.7.2014 and the company was awarded the relief in February,2016 and upward revision of ceiling price for the said formulation was given as Rs.1.63/tablet vide SO 582(E), dated 24.2.2016 and Rs.1.59/tablet (towards negative WPI reduction) vide SO 644(E), dated 2.3.2016. The company’s grievance is that NPPA took the MAT August,2015 PTR while fixing ceiling price in June, 2016, instead of taking the revised ceiling price granted to them in February/March, 2016. Hence, the contention of the petitioner company that taking MAT August,2015 PTR and ignoring February/March, 2016 price fixation by NPPA, while fixing ceiling price in June, 2016 has got merit. Therefore, NPPA may be directed to reconsider the fixation of ceiling price for Phenobarbitone 30 mg. tablet.”

Similarly, company had also challenged the price calculation for **Metronidazole infusion 500mg /100 ml** against SO 834(E) dt. 25th March, 2015 and the company was awarded the relief in Nov'2015 and an upward revision of ceiling price for the said formulation was given as Rs. 0.15 Per ml vide SO 3023(E), dated 09.11.2015 and Rs.0.14 Per ml (towards negative WPI reduction) vide SO 644(E), dated 2.3.2016.

The company’s grievance is that NPPA took the MAT August,2015 PTR while fixing ceiling price in June, 2016, instead of taking the revised ceiling price granted to them in November, 2015 . Hence, NPPA has also erred in this instance case by taking MAT August,2015 PTR and ignoring November, 2015 price fixation by NPPA, while fixing ceiling price in June, 2016.

Therefore, the company requested that NPPA may be directed to reconsider the fixation of ceiling price for **Metronidazole infusion 500mg /100 ml** along with WPI impact for the calendar year 2016.

5. NPPA representative stated that the ceiling prices of metronidazole 200mg and 500mg were fixed as per the data provided by AIOCD-AWACS / Pharmatrac for the month of August, 2015.

6. Examination:

NPPA has notified SO 1039(E), dated 1.4.2017 only for giving Annual Wholesale Price Index @ 1.97186% increase effective from 1.4.2017 to the scheduled formulations. The revision of ceiling prices are not against the review applications filed by the company.

Metronidazole Oral Liquid 200mg/5ml:

The company had filed review petition under para 31 of DPCO, 2013 against SO 3182(E), dated 7.10.2016 vide which NPPA notified the ceiling price of the subject formulation. The grievance of the company, that NPPA should not have notified the revision of the formulation under consideration, has no relevance as SO 1039(E), dt.1.4.2017 is issued only to give WPI increase effective from 1.4.2017 to all the scheduled formulations. The matter of revision of ceiling price will be considered on the outcome of review application filed earlier by the company against SO 3182(E), dated 7.10.2016.

Metronidazole 500mg/100ml:

The company had filed review petition under para 31 of DPCO, 2013 against SO 443(E), dated 14.02.2017 vide which NPPA notified the ceiling price of the subject formulation. The grievance of the company, that NPPA should not have notified the revision of the formulation under consideration, has no relevance as SO 1039(E), dt.1.4.2017 is issued only to give WPI increase effective from 1.4.2017 to all the scheduled formulations. The matter of revision of ceiling price will be considered on the outcome of review application filed by the company earlier against SO 3182(E), dated 7.10.2016.

7. Government Decision:

“NPPA notified SO 1039(E), dt.1.4.2017 to give WPI increase effective from 1.4.2017 only to all the scheduled formulations. It is not with reference to the review application filed by the company. The matter of revision of ceiling price of Metronidazole 500mg/100ml will be considered by NPPA on the basis of outcome of earlier review applications filed by M/s J.B. Chemicals & Pharmaceuticals Limited for the formulations Metronidazole Oral Liquid 200mg/5ml and Metronidazole 500mg/100ml.”

Issued on this date, the 28th day of September, 2017.

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

To

1. M/s. J.B. Chemicals & Pharmaceuticals Ltd.
“NEELAM CENTRE”, ‘B’ Wing, 4th Floor,
Hind Cycle Road, Worli,
Mumbai-400 030.

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