

No. 31015/51/2017-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 J.B. Chemicals & Pharmaceuticals Ltd. against price fixation of “Metronidazole Tablet 200mg and Metronidazole Tablet 400mg” vide NPPA order No. S.O. 1039(E), dated 01.04.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 19.04.2017
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. This is petition 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 Tablet 200mg and Metronidazole Tablet 400mg.

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 tablet 200mg and Metronidazole tablet 400mg at Sr. No. 441 and 440 under the provisions of Para 4 and 6 of Drugs (Prices Control) Order (DPCO), 2013.
- II. AND WHEREAS, the base ceiling price for METRONIDAZOLE TABLET 200MG and 400MG in accurately notified vide 2195(E) Dated 23rd June, 2016 and 1819(E) Dated 18th May, 2016 wherein NPPA had erred by considering the incorrect ceiling price of their formulation and the matter is current subjudice at Bombay high court.
- III. AND WHEREAS, The National Pharmaceutical Pricing Authority issued notification no. S.O. 2195 (E) dated 23rd June, 2016 and notification no.

S.O. 1819 (E) dated 18th May, 2016 notifying ceiling prices of Metronidazole tablet 200mg and Metronidazole tablet 400mg respectively under para 18 (1) and para 4 (1) of the Drugs (Prices Control) Order, 2013 (DPCO).

IV. AND WHEREAS the said notification no. S.O. 2195 (E) dated 23rd June, 2016 and notification no. S.O. 1819 (E) dated 18th May, 2016 was to be based on the Moving Annual Turnover of Major manufacturers as on August, 2015.

Under the circumstances:

- a. NPPA had erred in accurately notified the ceiling price of Metronidazole tablet 200mg and Metronidazole tablet 400mg as per the provision of PARA 4 vide S.O. No. 2195(E) Dated 23rd June 2016 and 1819(E) Dated 18th may, 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 the subjudice court case to be resolved.
- d. S.O. 2195 (E) states that it considers prices of Metronidazole 200 and S.O. 1816 (E) states that it considers prices of Metronidazole 400 mg tablets, both as at August, 2015 for calculation of revised ceiling price under the provisions of paragraph 4.
- e. The prices of Metronidazole 200 mg Tablets and Metronidazole 400 mg Tablets as prevalent in August, 2015 were governed by S.O. 834 (E) dated 25th March, 2015 and the ceiling price under S.O 834 (E) was erroneous as the full impact WPI increased was not allowed to the company. They also referred to Order by Reviewing Authority under Para 31 of DPCO, 2013 (no.31015/18/2015) dated 8th September, 2015.
- f. The Order was passed against the aforesaid S.O. 834 (E) dated 25th March, 2015 and stated:

“NPPA is directed to revise prices of the subject formulation after the petitioner has availed WPI in December, 2014 as per provisions of Para 9(6) and 10 (2) of DPCO, 2013. The Company will be entitled for WPI again w.e.f 1.4.2015”.

Further, NPPA had notified revised ceiling prices vide S.O. 3023 (E) dated 9th November, 2015, in supersession of S.O. 834 (E) dated 25th March, 2015.

- V. Having been aggrieved by the fact that the captioned formulations were priced at INR. 0.46 and INR. 0.83 plus local taxes per tablet with effect from 1st April, 2015 and yet NPPA has once again committed an error of principal and to maintain equity of justice, the ceiling price of Metronidazole 200 mg Tablets and Metronidazole 400 mg Tablets should be calculated considering the Order by Reviewing Authority dated 8th September, 2015 and S.O. 3023 (E) dated 9th November, 2015.
- VI. In view of above, applicant prayed as under:-
- a. To consider and conclude that NPPA had erred in pricing of their formulations Metronidazole 200 mg Tablets and Metronidazole 400 mg under Notification no. S.O. 1039 (E) dated 01st April, 2017.
 - b. To consider and conclude that NPPA must revise the ceiling price of the Metronidazole 200 mg Tablets and Metronidazole 400 mg in accordance with provisions of Para 4 of DPCO, 2013 considering all SKUs having market share more than 1%.
 - c. Pass a speaking order in respect hereof.
 - d. Any other order in interest of this manufacturer.

Comments of NPPA:

- I. Ceiling price of **Metronidazole Tablet 400mg** was notified as Rs. 0.75/tablet vide S.O. 1819(E) dated 18.05.2016 and revised to Rs. 0.76/tablet vide S.O. 1039(E) dated 01.04.2017 and ceiling price of **Metronidazole Tablet 200mg** was notified as Rs. 0.40/tablet vide S.O. 2195(E) dated 23.06.2016 and revised to Rs. 0.41/tablet 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 Tablet 400mg and Metronidazole Tablet 200mg**. 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 31st Authority meeting held on 18.05.2016 and as per the decisions of 33rd meeting held on 23.06.2016 respectively. Details are as follows:-

| S. No. | Company's Grievances | NPPA's comments |
|--------|--|---|
| 1. | <p>The company has pointed out that base ceiling price for Metronidazole Tablet 200mg and Metronidazole Tablet 400mg fixed by NPPA vide S.O. 2195(E) dated 23.06.2016 and S.O. 1819(E) dated 18.05.2016 is not correct as NPPA has considered the incorrect data for calculating the ceiling price. Company has also pointed out that the matter is subjudice at Bombay High Court.</p> <p>2. 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>3. NPPA must first correct the base ceiling price in accordance with para 4 of DPCO, 2013 or wait for the decision of the Court.</p> <p>4. The ceiling prices of Metronidazole Tablet 200mg and Metronidazole Tablet 400mg as prevalent in August 2015 were governed by S.O. 834(E) dated 25.03.2015. The impact of WPI increased was not applicable to the formulations in the light of review order no. 31015/18/2015 dated 08.09.2015.</p> <p>5. The ceiling price Metronidazole 200mg tablet and Metronidazole 400mg tablet should be calculated considering the review order no. 31015/18/2015 dated 08.09.2015.</p> | <p>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>Based on the review order no. 31015/18/2015-PI.I dated 08.09.2015, the ceiling price of Metronidazole tablet 400mg and Metronidazole tablet 200mg was revised to Rs. 0.46 and Rs. 0.83 on 09.11.2015, and the revised price was applicable from that date (and not retrospectively).</p> <p>M/s J.B. Chemicals filed review application against S.O. 3023(E) dated 09.11.2015 in respect of Metronidazole Tablet 400mg and Metronidazole Tablet 200mg. Review petition under reference was rejected by DOP vide order no. 31015/36/2015-PI.I dated 03.08.2016.</p> <p>While fixing the ceiling price of subject formulations under NLEM 2015, August 2015 data was considered as per provisions of para 9(5) of DPCO, 2013.</p> |
| | | <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. Chemicals:-</p> <p>1. Metronidazole Tablet 400mg 10's – 27.69%</p> <p>2. Metronidazole Tablet 400mg 15's – 25.64%</p> |

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|--|--|--|
| | | 3. Metronidazole Tablet 200mg 10's – 32.44% |
| | | 4. Metronidazole Tablet 200mg 100's – 25.72% |
| | | 5. Metronidazole Tablet 200mg 5's – 32.44% |

III. Company stated that they have filed writ petition against S.O. 2195(E) dated 23.06.2016 and S.O. 1819(E) dated 18.05.2016 in respect of Metronidazole based formulation at Bombay High Court.

3. During the personal hearing, the representatives of the company, in addition to their earlier submissions, stated that NPPA had erred by notifying under Para 4 considering the prices prevalent in Aug'2015 inspite 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, the company had also challenged the price calculation for Metronidazole Tab 200mg & Metronidazole tab 400mg against SO 834(E) dt. 25nd Mar'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 Metronidazole 200mg Rs0.46 and Metronidazole 400mg Rs,0.83 tablet vide SO 3023(E), dated 09.11.2016 and Metronidazole 200mg Rs 0.45 and Metronidazole 400mg Rs. 0.81 tablet (towards negative WPI reduction) vide SO 644(E), dated 2.3.2016.

The company's grievance is exactly the same, 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.

Further, the price per unit both Metronidazole 200mg and 400mg tablets differ from the actual invoices in August 15.

Therefore, the company requested that NPPA may be directed to reconsider the fixation of ceiling price for Metronidazole 200mg and 400mg tablets as notified in November, 2015 and not as implemented in August, 2015 due to error in NPPA working, along with WPI impact for the calendar year 2016.

For ready reference, the company submitted the sequence of events in tabulated form for Metrogyl 200mg & Metrogyl 400mg.

| Sequence of price applications, notifications, review application and orders for Metronidazole-200 mg | | | | |
|--|------------------------|---|----------------------|--|
| Date | S.O. / File No. | Event | Ceiling Price | |
| March 25, 2015 | 834 (E) | Price notified with WPI increase @ 3.84% instead of 10.4027% | 0.430 | |
| April 6, 2015 | | Review Petition filed against 834 (E) | | |
| May 8, 2015 | | Personal Hearing with DOP | | |
| September 8, 2015 | 31015/18/2015 | Directed NPPA to allow WPI increase of 2013 @ 6.32% and 2014 @ 3.84% w.e.f. 1.4.2015 | | |
| October 7, 2015 | | Reminder Letter to NPPA for price as per DoP directive | | |
| November 9, 2015 | 3023 (E) | Price notified under para 4 (1) - <u>to be effective from April 1, 2015</u> | 0.460 | |
| March 2, 2016 | 644 (E) | Ceiling Price reduce by WPI @ - 2.7105% | 0.450 | |
| June 23, 2016 | 2195 (E) | Price notified under para 4 (1) | 0.400 | the base of this calculation taken as 0.40 instead of .45 paise. Thus the derived the ceiling PTR should be 0.42 paise instead of 0.40 paise per tab |
| July 6, 2016 | | written to NPPA JB/AP/1611 | | |
| Oct 7, 2016 | | written to DOP JBCPL/AP/1 | | |
| Nov 29, 2016 | | written to DOP JBCPL/AP/VS/12 | | |
| April'17 | 1039(E) | WPI increase of 1.97% | 0.410 | This increase was erroneously given on 0.40 instead of 0.42 . The corrected figure should have been 0.43 per tablet. |

| Sequence of price applications, notifications, review application and orders for Metronidazole- 400 mg | | | | |
|--|-----------------|---|---------------|--|
| Date | S.O. / File No. | Event | Ceiling Price | |
| March 25, 2015 | 834 (E) | Price notified with WPI increase @ 3.84% instead of 10.4027% | 0.780 | |
| April 6, 2015 | | Review Petition filed against 834 (E) | | |
| May 8, 2015 | | Personal Hearing with DOP | | |
| September 8, 2015 | 31015/18/2015 | Directed NPPA to allow WPI increase of 2013 @ 6.32% and 2014 @ 3.84% w.e.f. 1.4.2015 | | |
| October 7, 2015 | | Reminder Letter to NPPA for price as per DoP directive | | |
| November 9, 2015 | 3023 (E) | Price notified under para 4 (1) - <u>to be effective from April 1, 2015</u> | 0.830 | |
| March 2, 2016 | 644 (E) | Ceiling Price reduce by WPI @ - 2.7105% | 0.810 | |
| May 18th 2016 | 1816 (E) | Price notified under para 4 (1) | 0.750 | since the PTR was wrongly considered as Rs. 10.09 instead of Rs.10.73 which was based on Sept'15 SO. By considering the PTR as 10.73/- per tab the notified price should come to Rs.0.81/- per tab |
| July 6, 2016 | | written to NPPA JB/AP/1611 | | |
| Oct 7, 2016 | | written to DOP JBCPL/AP/1 | | |
| Nov 29, 2016 | | written to DOP JBCPL/AP/VS/12 | | |
| April'17 | 1039(E) | WPI increase of 1.97% | 0.760 | This increase was erroneously given on Rs.0.75 instead of Rs.0.81 . The correct figure should have been Rs. 0.83 per tablet. |
| | | | | |

4. In addition to the reply submitted above, NPPA representative further stated that the ceiling price of metronidazole 200mg and 400mg tablets was fixed as per the data provided by AIOCD-AWACS / Pharmatrac for the month of August, 2015.

5. **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.

5.2 The company had filed review petition under para 31 of DPCO, 2013 against ceiling price fixation by NPPA for the formulations Metronidazole tablet 400 mg and 200 mg and based on DoP's Review Order No.31015/18/2015-PI.I., dated 08.09.2015, NPPA revised the ceiling price of both the formulations vide SO 3023(E), dated 9.11.2015. Company again filed review petition against SO 3023(E), dated 9.11.2015 which was rejected by DoP vide its Review Order No.31015/36/2015-PI.I, dated 3.8.2016. The company in para 3 of its review petition has stated that they have filed writ petition against SO 2195(E), dated 23.6.2016 and SO 1819(E), dated 18.5.2016 in respect of Metronidazole based formulation at Bombay High Court.

5.3 The grievance of the company that NPPA should not have notified the revision of the formulation under consideration without correcting the base ceiling price in accordance with para 4 of DPCO 2013 or wait for the Court decision, **has no relevance as SO 1039(E), dt.1.4.2017 is issued to revise the ceiling prices of all the scheduled formulations for only giving WPI increase effective from 1.4.2017. The SO is not meant to refix the ceiling price of any formulation.**

6. **Government Decision:**

“NPPA notified SO 1039(E), dt.1.4.2017 only to give WPI increase effective from 1.4.2017 to all the scheduled formulations and not meant to re-fix the ceiling price of any formulation. Therefore, the grievances raised by the petitioner company have got no relevance.”

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