

No. 31015/22/2017-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-500mg/100ml" vide NPPA order No. S.O. 443(E), dated 14.02.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 16.02.2017
2) NPPA notification under review S.O. 443(E), dated 14.02.2017
3) Record Note of discussions held in the personal hearing held in the matter on 13.06.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s J.B. Chemicals & Pharmaceuticals Ltd. (hereinafter called the petitioner) against notification S.O. No.443(E), dated 14.02.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Metronidazole-500mg/100ml

2. The petitioner has contended as under:-

- I. National Pharmaceutical Pricing Authority (NPPA) issued notification no S.O. 644(E) dated 2nd March 2016 fixing prices of, METRONIDAZOLE -500MG/100ML after giving effect of decrease in Wholesale Price Index (WPI) for the calendar year January to December, 2015 @ 2.7105%.
- II. WHEREAS NPPA issued a notification no S.O. 443 (E) dated 14THFebruary, 2017, fixing prices of 30 Scheduled formulations, inter-alia, including Price of Scheduled formulations "METROGYL INJECTION 100ML", each containing METRONIDAZOLE -500MG/100ML at serial no. 22 after giving effect of reduction in Wholesale Price Index (WPI) for the calendar year January to December, 2015.
- III. WHEREAS the said notification no. S.O. 443 (E) dated 14thFebruary, 2016 was to be based on the Moving Annual Turnover of Major manufacturers as on August, 2015.
- IV. WHEREAS ceiling price notified for formulation METRONIDAZOLE -500MG/100ML, as shared in NPPA's worksheet had the following errors:
 - a. The price to retailer of METROGYL INJECTION 100ML was erroneously considered as INR 12.07 instead of current prevailing price to retailer INR 12.58.
- V. WHEREAS, the company had written letter to NPPA dated 30th November 2016 requesting correction to the draft price calculation sheet of Metronidazole IV

500mg/100ml within 10 days from the issue of OM dated 28th November 2016 for the display of draft version of Proposed Price calculation sheets of 4 proposed revised/notified ceiling price /retail price on NPPA's website.

- VI.** WHEREAS, pursuant to aforesaid letter, this applicant JBCPL submitted a further additional submission vide letter dated 9th February 2017, in regards to the revised guidelines issued by NPPA, requesting price correction in calculation sheet of Metronidazole IV 500mg/100ml.
- VII.** WHEREAS, despite above submission NPPA has not considered the company's formal requests for correction of the error in price calculation sheet used in the calculation ceiling prices of their aforesaid formulations and no communication has been received either accepting or rejecting the aforesaid letters. Their letters have failed to receive attention from the concerned officials.

Under the circumstances:

- a. The Price to Retailer for METROGYL INJECTION 100ML, was erroneously considered to INR 12.07 instead of INR 12.58 despite submission of all relevant document for price correction from the manufacturers as required under the OM no 8(34)/2014/Div.II/NPPA dated 07thFebruary 2017.
- b. NPPA has failed to act on its own OM no 8(34)/2014/Div.II/NPPA despite timely submission of required supporting documents/information relating to Price to Retailer (PTR) and Moving Annual Turnover (MAT) data for the month of August 2015 required for correction in proposed price Calculation Sheets for Proposed revised/notified ceiling price/retail price on NPPA's website.
- VIII.** Having been aggrieved by the fact that the ceiling price of the captioned formulation Metronidazole IV 500mg /100ml is not correctly notified under S.O. 644(E) dated 14thFebruary, 2017 due to erroneously considering incorrect Price to Retailer as mentioned hereinabove.
- IX.** In view of above, Company has prayed as under:-
- (i) To consider and conclude that Ceiling Price of "METRONIDAZOLE - 500MG/100ML" as notified vide S.O 443(E) dated 14thFebruary, 2017 is incorrect and should be withdrawn with immediate effect and re-notified post rectification of calculation.
- (ii) To direct NPPA to notify the correct prices of METRONIDAZOLE -500MG/100ML within 15 days to avoid further undue punishment to the company.
- (iii) It has been advised by NPPA that Department of Pharmaceuticals superseded the Authority Committee and NPPA and thus, price notification under order of Department of Pharmaceuticals must not be delayed due to lack of Authority Committee meeting or otherwise and NPPA may please be directed to notify the correct prices of Metronidazole 500MG/100ml within 15 days to avoid further undue punishment to the company.

- (iv) Pass a speaking order in respect hereof.
- (v) Any other order in interest of this manufacturer.

Comments of NPPA:

- I. Company has stated that correct methodology was not followed in arriving at the ceiling price for **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. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has pointed out that NPPA has fixed ceiling price Rs. 0.14593/ml and Rs. 0.12039/ml vide S.O. 644(E) & 443(E) dated 02.3.2016 & 14.02.2017 by allowing the effect of reduction in Wholesale Price Index (WPI).	NPPA has fixed the ceiling price (i) Rs. 0.14593/ml vide S.O. 644(E) dated 02.3.2016 under NLEM 2011. (ii) 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. NPPA has been following this practice consistently since 10.3.2016.
2.	NPPA considered PTR Rs. 12.07 instead of current prevalent PTR RS.12.58.	NPPA considered the PTR provided by pharmatrac for the month of August, 2015.
3.	Company written a letter to NPPA against draft version of proposed price calculation sheet and also submitted additional submission requesting for price correction in calculation sheet of Metronidazole 500mg/100ml Injection.	Company's letter along with additional submission was examined but not considered by the Authority, since the company has not submitted the requisite documents as per OM dated 10.10.2016 within 10 days of the display of draft working sheet in NPPA's website. IPDMS compliance of the company was to the extent of 91% at that time, hence rejected.

- II. Company has not challenged any notification in respect of **Metronidazole 500mg/100ml Injection** in the Court.

3. During the personal hearing, the representatives of the company, in addition to their earlier submissions, stated that in response to the Office Memorandum No. 8(35)/2016/DP/(NPPA)-Div.II dated 28.11.2016 issued by NPPA the company had submitted its objections to the draft price calculation sheet dated 29th November, 2016

vide its letter dated 30th November, 2016 in which the company had enclosed the review order dated 8th September, 2015 issued by the Ministry, MAT value of the formulation, form V data submitted on the IPDMS, and more importantly the price/WPI basis agreed by the Ministry in its Review Order dated 8th September, 2015.

The company representative read out the following operative portion of the order dated 8th September, 2015:-

“NPPA is directed to revise the prices of the subject formulations after the petitioner had availed WPI in December, 2014 as per the 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.”

The Company further submitted that:

1. The ceiling price for Metronidazole injection 500 mg/100 ml as notified vide SO 834 (E) dated 25.03.2015 did not consider WPI increases as per para 10(2) of DPCO, 2013. As per para 10(2), where ceiling price of formulation was fixed after May, 2012, WPI increase was to be given on expiry of period of one year and also on 1st April of the following year. The Company was thus entitled for WPI increase on completion of one year (i.e. 21.12.2014) as well as on 01.04.2015. NPPA did not consider second WPI increase that was due to the Company on 01.04.2015.
2. On review petition filed by the Company, DOP decided in favour of the Company and NPPA was asked to revise the price vide order dated 08.09.2015. NPPA then corrected/revised the price vide SO 3023 dated 9th Nov. 2015. As per order passed by DOP, the Company was entitled for the increase w.e.f. 01.04.2015.
3. Therefore, the MAT as on August, 2015 (for the purpose of fixation of ceiling price under SO 443 (E) dated 14-2-17) should be based on the ceiling price notified vide S.O. 3023 dated 09.11.2015 and not S.O. 834(E) dated 25.3.2015 as NPPA has committed errors in calculating ceiling price notified under S.O. 834 (E) dated 25.03.2015.
4. In view of the above, the ceiling price fixed under S.O. 443(E) dated 14.02.2017 was also erroneous as it used MAT of major manufacturers as on Aug, 2015 which was derived from wrong ceiling price notified vide S.O. 834(E) rather than MAT derived from ceiling price fixed vide S.O. 3023 dated 9th Nov. 2015.
5. **Company should not be made victim of NPPA errors as the Company is losing revenues due to this error. The benefit granted by the Ministry as per the provisions of DPCO has been intentionally withdrawn by NPPA.**
6. Further, the price correction asked for vide review petition dated 16.2.2017 does not amount to retrospective price correction, we have asked DOP to rectify the error of NPPA and rectified price is for future sales by the Company.

- 7. The company once again emphasized that what we have requested NPPA/DOP is not retrospective price fixation but correction of errors committed in the past. This cannot be called retrospective price fixation as the corrected price will be applicable prospectively from the date of notification revising the ceiling price as requested.**

The company representative mentioned that price based on any entitlement which has been granted by the Reviewing Authority (i.e. the Hon'ble Minister) w.e.f. 1.4.2015 will remain the same in August, 2015 also.

In regard to the argument of NPPA that no notification is issued from a retrospective date the company representative mentioned that NPPA 's price basis from Pharma Track is based on the notifications S.O. 834(E) dated 25th March, 2016 which has been superseded by NPPA itself vide S.O. 3023(E) dated 9th November, 2015. The company representative further wanted to know the meaning of the word "entitlement" of WPI in December, 2014 and again w.e.f. 1.4.2015 mentioned in the Review order dated 8th September, 2015 if they are not to be honoured by NPPA. NPPA has no such authority to implicitly or explicitly withdraw the grant of WPI by the Reviewing Authority.

It is submitted that data used in notification S.O. No. 834(E) dated 25th March, 2015 i.e. August 2014 data may be used in this case and subsequent WPIs as ordered by the Reviewing authority in its order dated 8th September, 2015 i.e. in December, 2014 (WPI of 2013 @ 6.32%) and April 2015 (WPI of 2014 @ 3.84%) may be given as per the orders of the Reviewing authority dated 8th September, 2015.

We are following the MRP of the product as notified by NPPA from time to time and also following the provisions of Para 4, Para 7 with respect to Price to Retailer.

The Price to stockist that the company has to provide is inclusive of multiple variables including cash discounts for advance payment, bulk order discount for institution and no expiry return on sales.

While selling the product at discounted rate, we have not violated the provision of Para 4, Para 7 or any other provision of DPCO 2013. "

It is humbly submitted that the Ministry may honour its earlier order dated 8th September, 2015 and issue a suitable order in favour of the company.

The NPPA representative submitted that the ceiling price of Metronidazole 500mg/100 ml injection was fixed based on the prevailing price as on August 2015 as per Pharmatrac data in accordance with the para 9(5) of DPCO, 2013.

Based on the review order no. 8th September, 2015, the ceiling price of Metronidazole 500mg/100ml was revised and notified vide so. 3023 (E) dated 09.11.2015.

As per Pharmatrac data for the month of August 2015, the PTS and MRP (including VAT of 5%) of the product "Metrogyl IV 500mg infusion 100ml" of JB Chemicals & Pharmaceuticals are Rs. 9.50 and Rs. 14.70 respectively. Accordingly, the trade margin from PTS excluding VAT is 47.37%.

5. Examination:

The petitioner company has challenged the NPPA Order S.O. 443(E), dated 14.02.2017 for price fixation of their formulation **Metronidazole-500mg/100ml** on the ground that the PTR of their formulation Metrogl Injection 100ml was erroneously considered as Rs.12.07/100ml instead of current prevailing PTR of Rs.12.58/100ml.

The ceiling price of **Metronidazole-500mg/100ml** was fixed at Rs.0.14/ml (inclusive of excise duty and all taxes), vide Notification SO 834(E), dated 25.3.2015, which was challenged by M/s J.B. Chemicals. DoP, vide its Review Order, (31015/18/2015-PI.I, dated 08.09.2015), directed NPPA to re-fix the ceiling price of the subject formulation. NPPA revised the ceiling price of Metronidazole-500mg/100ml to Rs.0.15/ml (inclusive of excise duty and all taxes) vide Notification SO 3023(E), dated 9th November, 2015.

In view of the above, the grievance of the petitioner company that NPPA has considered the PTR of August, 2015 instead of taking the revised PTR granted to the company in November, 2015 based on DoP's Review Order, dated 8th September, 2015, has got merit. Therefore, NPPA may be directed to reconsider the re-fixation of ceiling price for Metronidazole Injection 500mg/100ml by considering the company's revised PTR of November, 2015.

7. Government Decision:

“NPPA is hereby directed to re-fix the ceiling price for Metronidazole Injection 500mg/100ml by considering company's revised PTR of November, 2015, granted to the company vide Notification SO 3023(E), dated 9th November, 2015 based on DoP's Review Order, dated 8th September, 2015.”

Issued on this date, the 24th day of August, 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