

No. 31015/36/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s. J.B. Chemicals Ltd. against fixation/revision of ceiling prices of Metronidazole tablet 200 mg and Metronidazole tablet 400 mg. vide NPPA notification S.O. No. 3023(E) dated 9/11/2015 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant's Review application dated 17.11.2015
2) NPPA notification under review S.O. No. 3023(E) dated 9.11.2015
3) Record Note of discussions held in the personal hearings held in the matter on 20.6.2016.

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 3023(E) dated 9.11.2015 fixed/revised ceiling price of Metronidazole Tablet 200 mg and Metronidazole Tablet 400 mg under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/s J.B. Chemicals Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 17.11.2015 under para 31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 3023(E) dated 9.11.2015 fixing Ceiling price of Metronidazole Tablet 200 mg and Metronidazole Tablet 400 mg under DPCO, 2013

3. The grievance of the Petitioner raised in their review application dated 17.11.2015 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the record note of discussions held in the personal hearing on 20.6.2016. Record note of discussion is made integral part of the review order. After considering the comments of NPPA based on points raised by the petitioner and the comments given by NPPA representative during the hearing and Department's comments on the issue is recorded subsequently against each point:-

Company: The working sheet related to the prices notified and observe that the source of data is Pharma Trac & Company and that NPPA have used MAT September, 2014 and PRT September, 2014 as the basis in calculating the notified prices and also the prices announced are not in line with DPCO, 2013. The company has already implemented prices fixed and announced by NPPA vide their S.O. No. 3023(E) dated 9th November, 2015.

NPPA: The main contention of the company is that the price fixed by the NPPA vide SO No. 3023(E) dated 09/11/2015 is not in line with the DPCO, 2013. In this regard, it is stated that ceiling price has been fixed as per paragraph 4,10,11,14 and 16 of the DPCO, 2013 and WPI increase for the year 2013 @ 6.32% and for the year 2014

@ 3.849% has been allowed while fixing the final worked out ceiling price for Metronidazole 200mg tablet at Rs. 0.46 per tablet and Metronidazole 400mg tablet at Rs. 0.83 per tablet, in view of the DOP's order dated 08.09.2015. The ceiling price of above said formulations was fixed in 10th meeting of the Authority held on 20/12/2015 & notified vide S.O. 3788(E) dated 20/12/2013 on the basis of review order No. 31015/18/2013-PI.I dated 27/11/2013 issued by this Department in the above mentioned company and this notified price remained effective for one year (i.e. upto 19.12.2014). The ceiling price of above said common formulations was again notified at Rs. 0.43/tablet & RS. 0.78/tablet for Metronidazole 200mg & 400mg tablet respectively vide S.O. No. 834(E) dated 20/03/2015 on the basis September, 2014 data (i.e. 6 months earlier as per para 9 of DPCO, 2013). It is also mentioned by NPPA that since the ceiling price was fixed after allowing after WPI for the year 2014 @ 3.849% for the first under DPCO, 2013 to be effective from 01/04/2015. Again these ceiling prices were notified at Rs. 0.46/tablet & 0.83/tablet (with WPI) respectively vide SO No. 3023(E) dated 09/11/2015 on the basis of this Department review order No. 31015/18/2015-PI.I dated 08/09/2015.

4. During the personal hearing on 20.6.2016, the submission of the company representatives and NPPA are summarized below:

- (i) In accordance of para 10(2) of DPCO, 2013 the prices of the said formulations should have been increased as per the annual Whole sale price Index of the calendar year 2013 in December, 2014.
- (ii) Further, NPPA should have thereafter taken simple average market price for the said formulations and allowed for the annual wholesale price index of the calendar year 2014 in April,2015.
- (iii) However, as per SO No.834(E) dated 25.03.2015, NPPA first took simple average market price for the said formulations and then allowed for corresponding annual whole sale price index for the years 2013 and 2014.
- (iv) The difference in interpretation and working under para 10(2) of DPCO, 2013 led to a reduction in price of 0.5 paise per tablet.
- (v) Further, SO 3023(E) dated 09th November, 2015 was issued in accordance with review order F.No31015/18/2015 dated 8th September, 2015. The order read as under:
"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"
- (vi) NPPP, 2012 in paragraph 4(xi) states "the Simple Average Price of all the brands of the medicine having share (on the basis of Moving Annual Turnover) more than the equal to 1% of the total market turnover of that medicine – the Reference Prices for calculation of Simple Average Price – may also change on an annual basis due to changes in the MAT value. **However, there would be no annual revision of Ceiling Prices on the basis of MAT**". Thus, SO 1816 (E) cannot be implemented under para 4(1) of DPCO, 2013 within one year of SO 3023(E) dated 9th November, 2015.
- (vii) However, NPPA has not explicitly stated the SO 3023(E) to be effective from 1st April, 2015 and further considered the incorrect prices prevalent

under SO 834(E) as on August, 2015 in their simple average market price for the said formulations under SO 1816(E) dated 18th May, 2016.

- (viii) Considering the well established principle of “Peter cannot be made to pay for Paul”, the company should not be made to pay for NPPA’s errors.
- (ix) Consistent and repeated errors of NPPA as well as undue delay in price notification for the said formulations has resulted in the company not being allowed a just and legal price for a period of 30 months over the last 51 months.

Keeping in view the abovementioned facts, the company requested to consider and conclude that ceiling prices as notified vide SO 3023 (E) and subsequent SO 1816(E) are in contravention of para 10(2) of DPCO, 2013, NPPP, 2012 and the directive of review order dated 8th September, 2015

- (a) Considering the undue hardship to the company we request NPPA must notify corrected prices within 15 days.**
- (b) SO 1816(E) must consider the MAT post correct implementation of DoP directive and DPCO, 2013. Further, prices as at August, 2015 were applicable vide SO 834(E) and must be stated as incorrect.**
- (c) Pass a speaking order in respect thereof.**
- (d) Any other order in interest of this manufacturer.**

NPPA Representative’s comments:

Statement made by the Company representatives are misleading hence denied. NPPA has fixed the ceiling price Rs.0.83 per tablet for Metronidazole 400mg tablet. The ceiling price has been fixed as per para 4,10,11,14 and 16 of DPCO, 2013 and WPI increase for the year 2013 @6.32% and for the year 2014 @3.849% has been allowed while fixing the ceiling price in view of DoP’s review order dated 8.9.2015 as per the common practice.

As per provisions of para 10(2) of DPCO, 2013 after company has availed the WPI in December, 2014 the prices are to be refixed as per the formula given in sub-para 1 of para 4 of DPCO, 2013.

The impact of WPI is generally given based on the ceiling prices.

Examination:

5. Based on the review order dated 8.9.2015 issued by this Department on the review application of M/s J.B. Chemicals Ltd., NPPA has fixed the price of Metronidazole Tablet 200 mg. and 400 mg. vide SO No.3023(E) dated 9.11.2015. During the personal hearing on 10.12.2015, the company representative mentioned that on perusal of the calculation sheet, it is noted that NPPA has taken the average of the market prices instead of considering the ceiling plus WPI. In this regard, para 10(2) of DPCO 2013 states that – **“The price of scheduled formulations, which are also specified in the First Schedules to the Drugs (Price Control) Order, 1995, fixed and notified under the provisions of Drugs (Prices Control) Order,**

1995 after 31st May, 2012, shall remain effective for one year from the date of notification of such prices under Drugs (Prices Control) Order, 1995 and immediate thereafter the manufacturers may revise the prices as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and on the 1st April of succeeding financial year, the formula as in sub-paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling of such schedule formulations.”

6. Subject formulation is a common formulation both under DPCO 1995 and DPCO 2013. Prices fixed by NPPA in December, 2013 remained fixed for one year i.e. upto December, 2014. Based on the review order issued by this Department on 8.9.2015, NPPA revised the prices vide notification dated 9.11.2015 by allowing WPI availed by the company in December, 2014. The argument of the company is that NPPA while issuing notification dated 9.11.2015 should not have taken the average of the available prices and rather should have given WPI on the ceiling price. Company argument has no basis. It may be seen from provision of para 10(2) that after giving WPI for previous year on the 1st April of succeeding financial year, the formula mentioned in sub-para 1 of para 4 of DPCO 2013 shall be applied for fixing the ceiling prices of such scheduled formulations. It is clear that para 4(1) of DPCO 2013 provides for averaging of the market prices and, therefore, NPPA has correctly fixed the price of the said formulation vide notification dated 9.11.2015.

7. Based on the above and other documents on record, the Government has decided as under:

“The review application of the petitioner is rejected having no merits.”

Issued on this date, the 3rd of August, 2016.

(M.K. Bhardwaj)
Deputy Secretary

For and on behalf of the President of India

To

1. M/s J.B. Chemicals 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. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D, NIC for uploading the order on Department's Website.