

No. 31015/95/2016-PI.I
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 Limited against price fixation of Metronidazole Oral Liquid 200 mg/5 ml vide NPPA order No. S.O. 3182(E), dated 7.10.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 26.10.2016
2) NPPA notification under review S.O. No.3182(E) dated 7.10.2016
3) Record Note of discussions held in the personal hearing held in the matter on 27.12.2016.**

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 Limited (hereinafter called the petitioner) against notification S.O. No.3182(E) dated 7.10.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Metronidazole Oral Liquid 200 mg/5 ml.

2. The petitioner has contended as under:

- I. National Pharmaceutical Pricing Authority (hereinafter referred to as NPPA) under the Department of Pharmaceutical, Ministry of Chemicals and Fertilizers, Government of India issued a notification no S.O. No. 3182(E) dated 07/10/2016, revising ceiling price fixed vide S.O. 1561(E) dated 27/04/2016, fixing prices of scheduled formulations "METROGYL 200 mg suspension 30 ml" and "METROGYL 200 mg suspension 60 ml" each containing Metronidazole Oral Liquid 200MG/ 5 ML after giving effect of reduction in Wholesale Price Index (WPI) for the calendar year January to December, 2015.
- II. AND WHEREAS ceiling price notified for formulation Metronidazole Oral Liquid 200MG/ 5 ML, as shared in NPPA's worksheet for S.O. 1561(E) dated 27/04/2016, had the price of Metron 200 mg Suspension 30 ml being considered. However, the same was omitted from the working sheet for the S.O. 3182(E) dated 07/10/2016. And Whereas, the company had written three letters to NPPA dated 10/05/2016, 26/05/2016 and 01/07/2016 requesting correction of the ceiling price under direction of OM 19(714)/2016 dated 11/04/2016.
- III. Company further submitted that:-
 - a. it need to be appreciated that despite repeated reminder to NPPA, the ceiling price calculation has not been accurately rectified for over six (6) months.
 - b. There was no rational for not considering the price of Metron 200 mg suspension

30 ml when other pack of 60 ml was being considered.

c. Not considering Metron 200 mg suspension 30 ml has adversely affected the ceiling Price as notified vide S.O. 3182(E) dated 07/10/2016 and consequently the said notified price is not as per the provisions of Para 4 of DPCO, 2013.

IV. Having been aggrieved by the fact that the ceiling price of the captioned formulation Metronidazole Oral Liquid 200MG/ 5 ML was not correctly notified under S.O. 1561(E) dated 27/04/2016 and continues to be incorrect under S.O. 3182(E) dated 07/10/2016 due to omission of the pack size as mentioned hereinabove.

V. Company filed the Review Petition under Para 31 of the Drugs (Prices Control) Order, 2013 against S.O. 3182(E) dated 07/10/2016 and **request to pass a speaking order in the matter.**

VI. Under the circumstances, The Applicant PRAYED as under:

1. To consider and conclude that Ceiling Price of "Metronidazole Oral Liquid 200MG/ 5 ML" as notified vide S.O. 3182(E) dated 07/10/2016 is incorrect and needs to be rectified after considering Metron 200 mg Suspension 30 ml.

COMMENTS OF NPPA

(i) NPPA fixed the ceiling price Rs. 0.25/ml for **Metronidazole Oral Liquid 200mg/5ml** vide S.O. 1561(E) dated 27.4.2016 and the **same was revised to Rs.0.27/ml vide S.O. 3182(E) dated 07.10.2016** after examination & consideration of company's representation letters dated 10.5.2016, 26.5.2016 & 01.7.2016 in the light of para 9(1) of DPCO, 2013.

(ii) The company was informed by NPPA vide letter no 10(sec. 6.2.2.7.3)/2016/DP/Div.II/NPPA dated 16.5.2016 that NPPA had considered the data of all brands and all packs of (Flagyl & Metron) correctly as they are available in the AIOCD based data. The company could have represented to NPPA alongwith authenticated supporting document as required by the Office Memorandum dated 11.5.2016 uploaded on the NPPA's website. The same request was made to M/s Alkem Laboratories Ltd., M/s Abbott Healthcare Pvt. Ltd. & M/s J. B. Chemicals & Pharmaceuticals Ltd. vide letter no 10(sec. 6.2.2.7.3)/2016/DP/Div.II/NPPA dated 15.6.2016. After receipt of the information/data from the companies, it was sent to Pharmatrac via e-mail for confirmation/verification of the same. Pharmatrac analyzed the same and sent the verification report. Accordingly, the working sheet was updated/revised. The revised ceiling price of Metronidazole Oral Liquid 200mg/5ml was again notified to Rs. 0.27/ml vide S.O. 3182(E) dated 07.10.2016.

(iii) The request of M/s J. B. Chemicals Limited in para 4(a) of letter dated 26.7.2016 is not acceptable because of the following reasons:

(a) M/s Alkem Laboratories Limited had informed vide letter no ALL/PJP/193 dated 24.6.2016 that they are manufacturing / marketing Metron Suspension **60ml only** and the same was **confirmed by the Pharmatrac.**

(b) M/s J. B. Chemicals & Pharmaceuticals Limited vide letter dated 10.05.2016 & 26.5.2016 and M/s Abbott Healthcare Pvt. Ltd. vide letter dated 25.05.2016 filed representation/review for price revision of **Metronidazole Oral Liquid 200mg/5ml**. In respect of review petition by M/s Abbott Healthcare Pvt. Ltd., the Department had issued a review order no. 31015/35/2016-PI.I dated 14.9.2016 wherein NPPA was directed to re-fix the ceiling price of Metronidazole Oral Liquid 200mg/5ml subject to getting the authenticating documentary proof regarding discontinuation of Flagyl 200mg. Suspension 100mg.

(c) As mentioned above, the ceiling price of this formulation was revised to Rs.0.27/ml vide S.O. 3182(E) dated 07.10.2016 as per para 4, 11, 14, 16, 17 & 18 of DPCO, 2013 based on the data provided by Pharmatrac for the month of August, 2015. Thus, based on the facts, contention of the manufacturer is baseless and needs to be rejected.

3. During the personal hearing on 27.12.2016, the representatives of the company submitted as under:-

- (i) The company has never undertaken a review or been called for representation by NPPA. The company has on its own accord written to NPPA for correction of ceiling price notified under SO 1561(E), dated 27.4.2016.
- (ii) There are two corrections requested by the company – firstly “Metron suspension 30 ml” was a part of the work sheet as released for SO 1561(E), dated 27.4.2016, but not mentioned in the work sheet for SO 3182(E), dated 7.10.2016. Secondly, this being the first ceiling price for Metronidazole Oral liquid 200 mg./5ml, application of para 4 and para 16 simultaneously is bad in law and should be corrected.

3.2 To support their first claim, the company has shared a certificate from the Pharmatrac software of AWACS-AIOCD, dated 22.12.2016. Metron suspension 30 ml is clearly shown to have the required MAT value for its price to be considered under para 4 of DPCO 2013. NPPA's claim that M/s Alkem Laboratories Ltd. has stated that they have not manufactured the aforesaid formulation stands corrected by the Pharmatrac report. Further, while Alkem may not have manufactured the formulation since 2012, the sales of the formulation continue till expiry and its MAT value as on August, 2015 must be considered.

3.3 Additionally with respect to application of para 4 and para 16 simultaneously, the company humbly submitted that para 16 states that the Government shall revise ceiling prices of scheduled formulations as per **WPI on or before the 1st April every year and notify the same on the 1st day of April every year**. Considering, there was no ceiling price for the aforesaid formulation on the 1st of April, 2016, the question of revision under para 16 does not arise. NPPA has erred by revising the price along with the first implementation on 27.4.2016.

3.4 NPPA representative submitted that there is no further addition with regard to non-inclusion of Metron suspension 30 ml in the calculation of ceiling price of Metronidazole Oral liquid 200 mg/5ml. NPPA representative further submitted that the

impact of WPI as on 1st April, 2016 while fixing the ceiling price of Metronidazole Oral liquid 200 mg/5ml was given based on the decision of the Authority.

4. **Examination:**

On examination, it is found that the company has raised a grievance that NPPA has missed out the MAT data of Metron Suspension 30 ml, in the work sheet for SO 3182(E), dated 7.10.2016. NPPA submitted that M/s Alkem Laboratories Limited (the manufacturer/marketer of Metron Suspension) has confirmed that they are manufacturing Metron Suspension **60 ml only** (not 30ml, as stated by the petitioner company) and the same was confirmed by Pharmatrac also. The petitioner company submitted a documentary proof of AIOC-AWACS during the personal hearing, in support of their claim that market share of Metron 100 mg suspension 30 ml is having 1.0% in August, 2015 and should be considered while fixing ceiling price of the formulation. It is seen from the documentary proof that **the petitioner company has submitted the data of different strength, i.e. 100 mg., whereas the strength under consideration is 200 mg.** In view of this, there is no merit in the grievance of the company and may be rejected.

4.2 As regards company's contention that application of negative WPI @ -2.7105 while fixation of ceiling price of the formulations **Metronidazole Oral Liquid 200 mg/5 ml** is not in accordance with the provisions of DPCO, 2013, 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."

4.3 In this case, the product **Metronidazole Oral Liquid 200 mg/5 ml** has 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.

4.4 In view of the above, NPPA has fixed the ceiling price of **Metronidazole Oral Liquid 200 mg/5 ml** 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.

5. **Government Decision:**

"The issue raised by the petitioner company about missing out MAT data of Metron Suspension 30 ml of M/s Alkem Laboratories cannot be considered, as NPPA considered Pharmatrac data and also confirmation from M/s Alkem Laboratories."

"NPPA has fixed the ceiling price of Metronidazole Oral Liquid 200 mg/5 ml 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. J.B. Chemicals & Pharmaceuticals Limited
“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**