

No. 31015/15/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 09.02.2018, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s J.B. Chemicals & Pharmaceuticals Limited (hereinafter called the applicant) against notification S.O. 352(E), dated 23.01.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Metronidazole-500mg/100ml.

2. The applicant has contended as under:-

2.1 NPPA issued notification no S.O. 352(E) dated 23/01/2018 fixing prices of Metronidazole 500mg/100ml.

2.2 WHEREAS the said notification no. S.O. 352(E) dated 23rd January, 2018 was based on the Moving Annual Turnover of Major manufacturers having Moving Annual Turnover of 1% or more than 1% as on August, 2015, as per AWACS data.

2.3 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 METROGIS INFUSION 100 ML of Surya Pharmaceuticals was erroneously not considered inspite of having more than 1% market share as of Aug, 2015 with having price to retailer as Rs.12.93.

2.4 WHEREAS, the NPPA had not uploaded the working sheet prior of announcement of SO no 352(E) dated 23rd January 2018 company did not had chance to write to had NPPA before fixation of price.

Under the circumstances:

a. The Price to Retailer for METROGYL INJECTION 100ML, was erroneously considered to Rs.0.12140 per ml due to non consideration of price to retailer of 1 sku i.e METROGIS INFUSION 100 ML of Surya Pharmaceuticals inspite of having more than 1% market share, as per AWACS data of MAT Aug, 2015.

2.5 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. 352 (E) dated 23rd January, 2018 due to erroneously not considering brands having more than 1% market share as mentioned hereinabove.

2.6 JBCPL files this Review Petition under Para 31 of the Drugs (Prices Control) Order, 2013 against S.O. No. 352 (E) dated 23rd January, 2018 and request to pass a speaking order in the matter.

2.7 Under the circumstances, the Applicant prayed as under:-

- (i) To consider and conclude that Ceiling Price of "METRONIDAZOLE - 500MG/100ML" as notified vide S.O 352(E) dated 23rd January, 2018 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 be directed to notify the correct prices of Metronidazole 500MG/100ml within 15 days to avoid further undue punishment to the company.

3. Comments of NPPA:

3.1 Under NLEM 2015 NPPA fixed the ceiling price of Metronidazole 500mg/100ml injection at Rs 0.12039 per ml vide SO 443 (E) dated 14.02.2017 which was revised to Rs 0.11773 per ml vide SO 2058 (E) dated 30.06.2017 to give effect of WPI and GST.

3.2 The company went for review against SO 443 (E) dated 14.02.2017 with the contention that the PTR of their product for the month of August 2015 is not to be taken since the PTR of August 2015 was revised in Nov 2015 based on DoP's earlier review order dated 08.09.2015 (under NLEM, 2011). DoP vide its review order No 31015/22/2017-Pricing dated 24.08.2017 directed to refix the ceiling price of Metronidazole 500mg/100ml injection based on the Revised PTR of Nov 2015. Accordingly NPPA implemented the review order by revising the ceiling price to Rs 0.12140 per ml (earlier it was Rs 0.11773 per ml) vide SO 352 (E) dated 23.01.2018.

3.3 The petitioner company has again gone for review against SO 352 (E) dated 23.01.2018 with the contention that the product of Surya Pharmaceuticals "METROGIS INFUSION 100 ML" was not included while calculating the ceiling price of subject formulation. In this connection, it may be stated that the ceiling price of Metronidazole 500mg/100ml injection was calculated based on the data provided by Pharmatrac for the month of August 2015. However in the Pharmatrac data for the month of August 2015 (and even in December 2017) the product METROGIS INFUSION 100 ML of Surya Pharmaceuticals was mentioned but no strength was specified, hence the same was not considered while arriving the ceiling price.

3.4 The petitioner company did not raise all the issues at a time during review filing but raising the same on piecemeal basis against different notification, the notification dated 23.01.2018 challenged was issued in implementation of the review order wherein

the prices as revised in Nov 2015 was to be taken. The company can challenge this notification only if there is an error in the prices of Nov 2015, no fresh issue can be raised at this stage. Challenging the notification dated 23.01.2018 on a new ground needs to be rejected at the stage of admission itself.

4. Examination:

4.1 NPPA notified SO 352(E), dated 23.1.2018 to implement the review order No.31015/22/2017-Pricing, dated 24.8.2017, based on review application of M/s J.B. Chemicals & Pharmaceuticals Limited, against SO 443(E), dated 14.2.2017, to address the main contention of the company to consider the revised PTR of their product for the month of November, 2015. Now, company has challenged this notification on the ground that NPPA has not considered PTR of METROGIS INFUSION 100 ML of Surya Pharmaceuticals inspite of having more than 1% market share. The company did not raise all the issues at a time while filing review application and raised the issue on piecemeal basis against different notification. This is not acceptable and deserves rejection.

4.2 Moreover, the formulation of M/s Surya Pharmaceuticals is without having any strength mentioned in the data statement. As per revised schedule (NLEM 2015) of DPCO, 2013, Metronidazole Injection 500mg/100ml is scheduled formulation (Section 6.2.2.7). NPPA has fixed the ceiling price of Metronidazole Injection 100ml by considering the data of only those formulations having strength of 500mg. As per data provided by Pharmatrac, no strength is mentioned against the product METROGIS INFUSION 100 ML, containing Metronidazole, of Surya Pharmaceuticals. Therefore, NPPA has rightly not considered the product of Surya Pharmaceuticals for price fixation of Metronidazole Injection 500mg/100ml. Hence, the grievance of the company has got no merit and cannot be considered.

Decision:

“NPPA fixed and notified the ceiling price of Metronidazole Injection 500mg/100ml, which is a scheduled formulation in NLEM, 2015 of DPCO, 2013, by considering the data of only those formulations having strength of 500mg. No strength is mentioned against the product METROGIS INFUSION 100 ML of M/s Surya Pharmaceuticals. Therefore, the data of the product was not considered for price fixation. Hence, the grievance of the company has got no merit and review application stands rejected.”

Issued on this date, the 25th day of June, 2018.

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

Copy to:-

1. M/s J.B. Chemicals & Pharmaceuticals Limited, Cnergy IT Park, Unit A2, 3rd Floor, Unit A, 8th Floor, Appa Saheb Marathe Marg, Prabhadevi, Mumbai-400 025.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website