

No. 31015/78/2016-PLI
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 three review applications filed by M/s J.B. Chemicals & Pharmaceuticals Ltd. – (i) review application dated 27.7.2016 against the price notified by National Pharmaceutical Pricing Authority (NPPA) vide S.O. 1561(E), dated 27.04.2016 for their formulation “Ranitidine Oral Liquid 75mg/5ml”; (ii)&(iii) application dated 15.6.2016 and application dated 29th November, 2016 against price notification SO 1816(E), dated 18th May, 2016 and SO 2193(E), dated 23.6.2016 for formulations Metronidazole 400mg and Metronidazole 200mg respectively.

2. The applicant has contended as under:-

(i) Ranitidine Oral Liquid 75mg/5ml:

Ceiling price notified for formulation RANITIDINE ORAL LIQUID 75MG / 5ML, as shared in NPPA's worksheet had the following errors:

a. The data for RANTAC SYRUP 30 ML was not considered despite having a market share of 2.2% as on MAT August 2015 as per the AWACS letter dated 18th Jan 2017.

b. The price to retailer of Aciloc Liquid 100ml has also not been considered for calculation of Ceiling Price despite having a market share of 5.4% as on August 2015 as per the AWACS letter dated 18th Jan 2017.

c. To direct the NPPA for providing personal discussion with the company before the finalisation of revised ceiling price Ranitidine Oral Liquid 75mg/5ml.

(ii) Metronidazole 200mg Tabs:

Ceiling price notified for formulation METRONIDAZOLE – 200mg, as shared in NPPA's worksheet, had the following errors:

a. S.O. 2195 (E) considers prices of Metronidazole 200mg tablets (RS. 5.87 for pack of 15's tablets) as at August, 2015 for calculation of revised ceiling price under the provisions of Paragraph 4 instead of considering prices of Metronidazole 200mg tablets (RS. 5.95 for pack of 15's tablets) from S.O. 3023 (E) dated 9th Nov'15 which was issued based on the review order by Reviewing Authority under Para 31 of DPCO, 2013 (no 31015/18/2015) dated 8th September, 2015.

b. In the price calculation sheet of 2195(E) dated 23rd June'2016, 3 pack descriptions of Metrogyl 200mg tablet company JB Chemicals are being erroneously shown at S. No. 6, 7, 8. This is an error while considering the computation of ceiling price based on Aug-15 data. Company requested to consider only 1 pack description i.e. Metrogyl 200mg tablets 15 with Price to retailer RS. 5.95 (pack of 15's tablets).

c. In the price calculation sheet of 2195(E) dated 23rd June'2016 the Price to Retailer of Flagyl 200 MG tablets of 15's pack company M/s Abbott Healthcare Pvt Ltd is erroneously considered as RS. 5.21 (for pack of 15's tablet), and upward revision of price vide SO no 3023 dated 9th Nov'15 was not considered while computation of ceiling price through SO no 2195 (E) dated 23rd June'2016.

d. In the price calculation sheet of 2195(E) dated 23rd June'2016, at S.No 4 & 5 pack description of METRONIDAZOLE (JAG) 200MG TABLET 100 & METGYL 200 MG TABLET 100 both of JAGSONPAL PHARMACEUTICALS LTD are being erroneously considered for calculation of derived ceiling PTR, as these 2 brand are not an active brand. Thus these brands should not be considered for computation of Ceiling Price.

e. To direct the NPPA for providing personal discussion with the company before the finalisation of revised ceiling price METRONIDAZOLE 200mg tablets.

(iii) Metronidazole 400mg Tabs:

Ceiling price notified for formulation METRONIDAZOLE – 400 mg, as shared in NPPA's worksheet had the following errors:

a. S.O. 1816 (E) considers prices of Metronidazole 400mg tablets (RS. 10.09 for pack of 15's tablets) as at August,2015 for calculation of revised ceiling price under the provisions of Paragraph 4 instead of considering prices of Metronidazole 400mg tablets (RS.10.73 for pack of 15's tablets) from S.O.3023 (E) dated 9th Nov'15 which was issued based on the review order by Reviewing Authority under Para 31 of DPCO, 2013 (no 31015/18/2015) dated 8th September, 2015.

b. In the price calculation sheet of 1816(E) dated 18th May'2016 the Price to Retailer of Flagyl 400 MG tablets 15 company M/s Abbott Healthcare Pvt. Ltd is erroneously considered as RS. 9.46 (for pack of 15's tablet), as upward revision of price vide SO no 3023 dated 9th Nov'15 was not considered while computation of ceiling price through SO no 1816 (E) dated 18th May'2016.

c. To direct the NPPA for providing personal discussion with the company before the finalisation of revised ceiling price METRONIDAZOLE 400mg tablets.

3. COMMENTS OF NPPA

3.1 In this regard, it is stated that the ceiling prices of formulations fixed by NPPA, are detailed below:-

S. N o.	Name of the Formulation	Company's Product Composition	Notified Price (Rs)	S.O. & Date
1	Metronidazole 400mg Tablet	Each tablet contains: Metronidazole 400mg	Rs 0.75 per tablet	1816 (E) 18.05.2016

2	Metronidazole 200mg Tablet	Each tablet contains: Metronidazole 200mg	0.40 per tablet	2195 (E) 23.06.2016
3	Ranitidine Oral Liquid 75mg/5ml	Each 5 ml contains: Ranitidine 75 mg	0.54 per ml	1560 (E) 27.04.2016

In the review petition the company submitted sequence of events alongwith their remarks as their Grievances.

3.2 The Grievances of the company and NPPA's reply with respect to **Metronidazole 400mg Tablet and Metronidazole 200mg Tablet** are as follow:

(i) Company's Grievance:

After NLEM 2015, NPPA issued SO 1816(E) dated 18.05.2016, S.O. 2195 (E) dated 23.06.2016, fixing ceiling price of Metronidazole 400 mg at Rs. 0.75 per tablet, Metronidazole 200 mg at Rs. 0.40 per tablet using pharmatrac data of August 2015.

Company claimed that the price revised by NPPA in Nov, 2015 was the correct price to be considered while calculating the ceiling price vide SO 1819(E) dated 18.05.2016, S.O. 2195 (E) dated 23.06.2016. However NPPA considered the August 2015 price based on SO 834 E dated 25.03.2015 which was revised by DoP vide SO 3023 (E) dated 09.11.2015.

NPPA's Comments:

NPPA notified ceiling price of Metronidazole 400 mg tablet and Metronidazole 200 mg tablet at Rs 0.75 per tablet and Rs 0.40 per tablet respectively vide SO 1819 (E) dated 18.05.2016 and SO 2195 (E) dated 23.06.2016 considering the data submitted by the Pharmatrac for the period of August 2015. NPPA has been following this practice consistently as decided in 27th Authority meeting held on 29.03.2016 for price fixation of all scheduled formulations included in revised scheduled-I of DPCO, 2013. Hence, company's contention to include the PTR of Nov 2015 is not tenable.

(ii) Company's Grievance

In calculating ceiling price, NPPA has not considered PTR of two formulations viz. (1) JBCPL's product Rantac TM syrup 30 ml containing Ranitidine 75 mg/5ml having market share of more than 1% and (2) Aciloc TM liquid pack 100 ml., which was also having market share of 1%.

Company submitted its representation (against SO 1560(E) dated 27.04.2016) vide letter dated 10.05.2016 highlighting the error with the assumption that it would serve as review petition under para 31 of DPCO, 2013.

NPPA's Comments:

NPPA fixed ceiling price of Ranitidine Oral Liquid (Ranitidine-75 mg/5ml) at Rs.0.54 per ml vide SO 1560(E) dated 27.04.2016 considering the data submitted by Pharmatrac for the

period of August 2015. Since, formulations viz. (1) Rantac TM syrup 30 ml containing Ranitidine 75 mg/5ml and (2) Aciloc TM liquid pack 100 ml were not reflected in the data provided by pharmastrac hence could not be considered.

4. Examination:

(i) In case of Ranitidine Oral Liquid 75mg/ml:

NPPA fixed the ceiling price of Ranitidine Oral Liquid 75mg/ml vide SO 1561(E), dated 27th April, 2016 at Rs.0.54 per ml, by considering Pharmastrac data as on August, 2015. It is seen from the calculation sheet, the PTR of three companies were considered which were having MAT value of more than 1%. However, company claimed that its formulation RANTAC 75 mg SYRUP 30ML, which was having 2.2% market share with PTR of Rs.29.25 for 30ml, as on August, 2015, was not considered. Similarly, the data of Aciloc Only 150mg Syrup 100ml, being manufactured by Cadila Pharmaceuticals Ltd., having market share of 5.4% with PTR of Rs.61.60 for 100 ml was not considered. In support of its claim, the company furnished the letter, dated 18.1.2017 of AIOCD Pharmasofttech AWACS Pvt. Ltd. (Pharmastrac).

In view of the above, NPPA needs to be directed to examine the documentary proof submitted by the applicant company about market share of RANTAC 75 mg SYRUP 30ML and Aciloc Only 150mg Syrup 100ml of Cadila Pharmaceuticals Ltd., and after verification, if the claim of the company is found correct, re-fix the ceiling price of Ranitidine Oral Liquid 75/ml, on merit.

(ii) In case of Metronidazole 200mg tablets:

NPPA fixed the ceiling price of Metronidazole 200mg tablets vide SO 2193(E), dated 23rd June, 2016 at Rs.0.54 per tablet, by considering Pharmastrac data as on August, 2015.

The ceiling price of Metronidazole 200mg tablet was fixed at Rs.0.43 per tablet vide SO 834(E), dated 25th March, 2015, which was challenged by M/s J.B. Chemicals and M/s Abbott Healthcare Pvt. Ltd. DoP vide its Review Orders No.31015/18/2015-PLI, dated 8.9.2015 in respect of M/s J.B. Chemicals and No.31015/23/2015-PLI, dated 24.8.2015 in respect of M/s Abbott Healthcare Pvt. Ltd. directed NPPA to re-fix the ceiling price of the subject formulation. NPPA fixed the ceiling price of Metronidazole 200mg vide Notification SO 2193(E), dated 23rd June, 2016 by considering August, 2015 data. The grievance of the company that NPPA considered the PTR of August, 2015 instead of taking revised PTR granted to the company (as well as to M/s Abbott Healthcare Pvt. Ltd.) in November, 2015, has got merit.

In view of the above, NPPA needs to be directed to reconsider the re-fixation of ceiling price of Metronidazole 200mg tablet by considering the revised PTR of November, 2015, granted to the applicant company as well as to M/s Abbott Healthcare Pvt. Ltd. vide Notification SO 3023(E), dated 9th November, 2015 based on DoP's Review Orders, dated 8.9.2015 (M/s J.B. Chemicals & Pharmaceuticals Ltd.) and 24.8.2015 (M/s Abbott Healthcare Pvt. Ltd.).

The other grievances of the company regarding wrongly considering their three pack descriptions of Metrogyl 200mg tablet and also wrongly considering inactive pack description of JAGSONPAL PHARMACEUTICALS LTD, has got no merit as NPPA considered the Pharmastrac data of those formulations/brands having more than 1% market share.

(iii) In case of Metronidazole 400mg tablets:

NPPA fixed the ceiling price of Metronidazole 400mg tablets vide SO 1816(E), dated 18th May, 2016 at Rs.0.75 per tablet, by considering Pharmatrac data as on August, 2015.

The ceiling price of Metronidazole 400mg tablet was fixed at Rs.0.43 per tablet vide SO 834(E), dated 25th March, 2015, which was challenged by M/s J.B. Chemicals. DoP vide its Review Orders No.31015/18/2015-PLI, dated 8.9.2015 in respect of M/s J.B. Chemicals and 31015/23/2015-PLI, dated 24.8.2015 in respect of M/s Abbott Healthcare Pvt. Ltd. directed NPPA to re-fix the ceiling price of the subject formulation. NPPA fixed the ceiling price of Metronidazole 400mg vide Notification SO 1816(E), dated 18th May, 2016 by considering August, 2015 data. The grievance of the company that NPPA considered the PTR of August, 2015 instead of taking revised PTR granted to the company (as well as to M/s Abbott Healthcare Pvt. Ltd.) in November, 2015, has got merit.

In view of the above, NPPA needs to be directed to reconsider the re-fixation of ceiling price of Metronidazole 200mg tablet by considering the revised PTR of November, 2015, granted to the applicant company as well as to M/s Abbott Healthcare Pvt. Ltd. vide Notification SO 3023(E), dated 9th November, 2015 based on DoP's Review Orders, dated 8.9.2015 (M/s J.B. Chemicals & Pharmaceuticals Ltd.) and 24.8.2015 (M/s Abbott Healthcare Pvt. Ltd.).

5. Decision:

“NPPA is hereby directed to examine the documentary proof submitted by the applicant company about market share of RANTAC 75 mg SYRUP 30ML and Aciloc Only 150mg Syrup 100ml of Cadila Pharmaceuticals Ltd., and after verification, if the claim of the company is found correct, re-fix the ceiling price of Ranitidine Oral Liquid 75/ml, on merit.”

“NPPA is further directed to reconsider the re-fixation of ceiling prices of Metronidazole 200mg tablet and Metronidazole 400mg tablet by considering the revised PTR of November, 2015, granted to the applicant company as well as to M/s Abbott Healthcare Pvt. Ltd. vide Notification SO 3023(E), dated 9th November, 2015 based on DoP's Review Orders, dated 8.9.2015 (M/s J.B. Chemicals & Pharmaceuticals Ltd.) and 24.8.2015 (M/s Abbott Healthcare Pvt. Ltd.) within a period of 30 days from the date of issue of this order.”

Issued on this date, the 8th 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 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

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