

No. 31015/24/2018-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 12.03.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Win Medicare Pvt. Ltd. (hereinafter called the applicant) against notification S.O. No. 650(E), dated 13.02.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Povidone Iodine Solution.

2. The applicant has contended as under:-

2.1 The ceiling price of Povidone Iodine Solution 10% was earlier fixed vide S.O 443(E) dated 14.02.2017 at Rs.0.66 per ml. The said ceiling price fixation was challenged by the Company against which the following order was passed by DoP on 28.09.2017:

“NPPA is hereby directed to re-fix and re-notify the ceiling price of formulation Povidone Iodine 10% solution by considering the actual PTR of Betadine 10% solution (500ml) and Drez 10% Solution (100ml) and by excluding the PTR of Wokadine 10% solution 1000ml, having less than 1% market share, within 30 days of the issue of this Order and compliance report be sent to DoP.”

2.2 That pursuant to the aforesaid order dated 28.09.2017, a meeting of the members / officers of NPPA was conducted on 05.02.2018 and 08.02.2018 wherein the appropriate authority approved the revision in the ceiling price of the Povidone Iodine 10% Solution from Rs. 0.64 per ml to Rs. 0.76 per ml and subsequently S.O. dated 13.02.2018 was also published on the website of NPPA.

2.3 The aforesaid revision in the ceiling price of Povidone Iodine 10% Solution is incorrect and wrong since the same is complete disregard of the order passed by the Ld. DoP on 28.09.2017 wherein it was categorically mentioned that the ceiling price of Povidone Iodine 10% Solution be revised after taking into account the actual PTR of formulation manufactured by our Company and other formulations mentioned therein, however, the same has not been done and which has again resulted in fixation of incorrect ceiling price of Povidone Iodine 10% Solution.

2.4 Being aggrieved by the said revision in the ceiling price of the Povidone Iodine 10% Solution, Company is filing the present Review Petition challenging the ceiling price fixation vide S.O. dated 13.02.2018 qua the formulation of our Company i.e. Betadine (Povidone Iodine) Solution 10%.

2.5 Company previously also challenged the notification being S.O 443(E) dated 14.02.2017 whereby the ceiling price of Povidone Iodine Solution 10% (company's formulation being Betadine 10% Solution) was fixed at Rs.0.66 per ml on the basis of an incorrect and erroneous data in the working sheet published on the website of NPPA on 15.02.2017 which was earlier displayed as draft / proposed working sheet on the website of NPPA along with the Office Memorandum dated 26.10.2016. The grounds for filing the earlier review petition are as follows:

- (a) It is most humbly submitted that ceiling price of every scheduled formulation is fixed/revised in accordance with provisions Para 4 of the DPCO, 2013 wherein, first, the Average price to retailer is calculated which is "*Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine*) / (*Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.*)". The amount calculated herein above is then used to calculate the ceiling price as per the formula mentioned in the Step 2 of the Para 4 of the DPCO, 2013, however, if incorrect / wrong PTR / MAT / Price per unit is taken into consideration for various brands, then the price of such formulations is bound to be incorrect and wrong as is the case in the present review application.
- (b) Company submitted with the NPPA, a letter dated 17.03.2017 received from Pharma Trac, inter-alia acknowledging that the data (PTR and MRP) provided by their organisation to NPPA pertaining to our formulation as well as various other formulation using Povidone Iodine Solution 10% for manufacturing their formulation was incorrect and erroneous and further has clarified the correct PTR and MRP of various formulations including the formulation manufactured by the Company.
- (c) Company vide letters dated 07.11.2016 and 09.11.2016 communicated to NPPA that inadvertently wrong and incorrect PTR / Price per unit of our formulation Betadine 10% Solution with pack size 500 ml (at S. No. 11 in the working sheet) has been taken into account by NPPA and further provided the correct figures along with supporting documents inter-alia requesting for modification / revision of the said working sheet. However, despite providing all the relevant details including Form V, NPPA arbitrarily vide notification being S.O 443(E) dated 14.02.2017 wrongly fixed the ceiling price of Povidone Iodine Solution 10% at Rs.0.66 for 1 ml wherein they have admittedly failed to consider the correct PTR of our formulation.
- (d) The NPPA while uploading the data in the said working sheet has taken into account wrong and incorrect PTR / Price per unit of various formulations which are using Povidone Iodine 10% Solution for manufacturing their formulations. For example, the PTR of Drez 10% Solution with pack size 100 ml was wrongly mentioned as Rs.33.15 whereas the correct PTR of the said formulation pack size is Rs.79.44, the PTR of Wokadine 10% Solution with pack size 500 ml was wrongly mentioned as Rs.297.56, whereas the correct PTR of the said formulation pack size is Rs.320.96.

- (e) In addition to the above, the PTR of Wokadine 10% Solution with pack size 100 ml is mentioned as Rs.81.52, PTR of Wokadine 10% Solution with pack size 500 ml is mentioned as Rs.297.56 (though correct PTR is Rs.320.96) but the PTR of Wokadine 10% Solution with pack size 1000ml is mentioned as Rs.81.52 (which is illogical and baseless) and thus it is a matter of common parlance that if the size/quantity/volume of a product increases the price is bound to increase. It reflects that the whole process is purely mechanical and over and above when these infirmities were pointed out by us, the same were not considered without any justifiable cause. It was subsequently acknowledged by Pharma Trac in their letter dated 17.03.2017 that Wokadine 10% Solution (1000ml) pack was inactive during August 2015 i.e. it was not present in the market and therefore, the same cannot be included in the working sheet uploaded by NPPA, which further substantiates the argument of our Company that wrong / incorrect prices have been considered by NPPA while fixing the ceiling price of Povidone Iodine 10% Solution.

2.6 Company submitted that despite the fact that they provided the correct data i.e. PTR and MRP by submitting the Form V along with invoices, samples, as well as the letter dated 17.03.2017 received from Pharma Trac notifying the correct prices, the NPPA has revised the ceiling price of Povidone Iodine 10% Solution basis incorrect data. The revision in the ceiling price of Povidone Iodine 10% Solution is incorrect and wrong since the same is complete defiance of the order passed by the DoP on 28.09.2017 wherein it was categorically mentioned that the ceiling price of Povidone Iodine 10% Solution be revised after taking into account the actual PTR of formulation manufactured by the Company and other formulations mentioned therein, however, the same has not been done and which has again resulted in fixation of incorrect ceiling price of Povidone Iodine 10% Solution. The ceiling price fixation vide notification being S.O. dated 13.02.2018 is wrong and incorrect for the following reasons:

- (a) The alleged revision in ceiling price is erroneous and faulty for the reasons that the same is neither in compliance with the order dated 28.09.2017 passed by the DoP categorically stating the ceiling price of Povidone Iodine 10% Solution be re-notified after taking into account the correct PTR of formulation involved in the present case, which admittedly has not been done by the NPPA nor the same is in compliance with the Para 4 of the DPCO, 2013.
- (b) Despite providing all the relevant details including Form V and letter dated 17.03.2017 received from Pharma Trac, NPPA arbitrarily vide the notification being S.O. dated 13.02.2018 wrongly fixed the ceiling price of Povidone Iodine Solution 10% at Rs.0.76 per ml wherein they have failed to consider the correct PTR of our formulation.
- (c) The NPPA while uploading the S.O. dated 13.02.2018 has failed to upload / provide the working sheet and the calculation carried out while revising the ceiling price of Povidone Iodine 10% Solution.
- (d) It is imperative to state herein that even assuming (without admitting) that the ceiling prices of Povidone Iodine 10% Solution were revised on the basis the data (PTR) submitted by the Pharma Trac, in that case also, the ceiling price notified vide the notification being S.O. dated 13.02.2018 is incorrect and wrong.

- (e) It is hereby reiterated that during the relevant period of Aug'2015 when the aforesaid data was collected, the correct PTR of the formulation manufactured by the Company i.e. Betadine (Povidone Iodine) Solution 10% (500 ml pack) is mentioned in table herein below and the ceiling price of Povidone Iodine 10% Solution after taking into account the actual PTR of formulation manufactured by our Company and other formulations as mentioned in your order is calculated herein below:

Statement Showing Final Ceiling price as on August 2015			
Product Name	ML	PTR	PTR per ml
Soludine 10% Solution	100	79.92	0.80
Betadine 10% Solution	500	384.54	0.77
Betadine 10% Solution	100	80.8	0.81
Drez 10% Solution	500	328.38	0.66
Drez 10% Solution	100	78.42	0.78
Wokadine 10% Solution	100	81.52	0.82
Wokadine 10% Solution	500	297.56	0.60
Sum of Price units			5.24
No. of Packs considered			7.00
Average PTR			0.75
Add Retailer Margin 16%			0.12
Ceiling Price Without Local tax			0.87
WPI reduction @ -2.7105%			0.02
Ceiling Price			0.85
WPI increase wef 1.4.2017 @ 1.97186%			0.02
Ceiling Price Pre GST			0.87
Ceiling price post GST (0.95905)			0.83

The aforesaid table clearly shows that correct ceiling Price of Povidone Iodine 10% Solution shall be (Rs. 0.83).

2.7 Without prejudice to the above and under protest, our Company has complied with the notification being S.O. dated 13.02.2018 and the MRP of the Betadine Solution 10% has been revised in accordance with ceiling price fixation notification date 13.02.2018.

2.8 It is clear from the above that the revision in the ceiling price of Povidone Iodine 10% Solution is incorrect and wrong since the same is complete defiance of the order passed by the Ld. DoP on 28.09.2017. The DoP vide order dated 28.09.2017 interalia categorically directed as follows:

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 On perusal of the above table, it is seen that there is discrepancy in consideration of PTR of Betadine 10% solution (500ml) and Drez 10% Solution (100ml). As regards Wokadine 10% solution (1000 ml), the PTR of Wokadine 10% solution 100ml and of Wokadine 10% solution 1000ml is shown as the same, i.e. 81.52, which is illogical. Moreover, as seen in the calculation sheet, the market share of Wokadine 10% solution 1000ml is shown only as 0.43%, i.e. less than 1%, and should not have been considered while fixing the ceiling price.

“NPPA is hereby directed to re-fix and re-notify the ceiling price of formulation Povidone Iodine 10% solution by considering the actual PTR of Betadine 10% solution (500ml) and Drez 10% Solution (100ml) and by excluding the PTR of Wokadine 10% solution 1000ml, having less than 1% market share, within 30 days of the issue of this Order and compliance report be sent to DoP.”

2.9 Since, the order categorically states that the ceiling price of Povidone Iodine Solution 10% be revised after taking into account the actual PTR of formulation manufactured by our Company and other formulations mentioned therein, however, the ceiling price of Povidone Iodine Solution 10% has not been fixed in accordance with the aforesaid directions passed by the Ld. DoP.

2.10 Therefore, Company requested that the notification being S.O. dated 13.02.2018 be withdrawn and suitably amended qua their formulation Povidone Iodine Solution 10% after taking into account the correct PTR as has been mentioned herein above.

3. Comments of NPPA:

3.1 NPPA had earlier fixed ceiling price of Povidone Iodine Solution 10% at Rs.0.66 per ml vide S.O. 443(E) dated 14.02.2017.

3.2 Based on the review orders issued by DoP for Povidone Iodine Solution 10% vide review No 31015/34/2017-pricing dated 28.09.2017 in respect of M/s Win Medicare and 31015/20/2017-pricing dated 28.09.2017 in respect of M/s Wockhardt Ltd. the Authority examined all the matters in the review order in details and the confirmation/verification from Pharmatrac. Accordingly the Authority revised the ceiling price of Povidone Iodine 10% solution at Rs 0.76 per ml in its 54th Meeting held on 12.02.2018 vide SO 650(E) dated 13.02.2018.

3.3 The detailed breakup by which the ceiling price of Povidone Iodine 10% solution was revised towards implementation of review orders of M/s Win Medicare limited is given below-

Product	Break up of Review order given by DOP	Claim of the Company	Action taken by the Authority	Original working sheet	Revised working sheet
Betadine 10% solution 500ml	To consider the actual PTR of Betadine 10% solution 500ml	PTR as on August, 2015 is Rs 384.54	PTR of Rs. 370.29 was taken based on highest count as per Pharmatrac. PTR of Rs 384.54 is 2 nd highest count	Rs. 163.81	Rs 370.29

Drez 10% solution 100ml	To consider the actual PTR of Drez 10% solution 100ml	PTR as on August, 2015 is Rs 79.44	PTR of Rs 78.42 was taken based on highest count as per Pharmatrac. PTR of Rs 79.44 is having low count	Rs 33.15	Rs 78.42
Wokadine 10% solution 1000 ml	To exclude Wokadine 10% solution 1000 ml having less than 1% market share		The product was not excluded since the brand Wokadine have more than 1% market share. The same was done based on the 47 th Authority Meeting wherein it was decided that brands having 1% or more market share is to be considered	The product Wokadine 10% solution 1000 ml was included.	The product Wokadine 10% solution 1000 ml was included.

5. Examination:

5.1 NPPA considered the PTR of Rs.78.42 for Drez 10% solution (100ml) and Rs.297.56 for Wokadine 10% solution (500ml) respectively. The PTRs of the above formulations were taken on the basis of Pharmatrac data which were captured being on highest count. Capturing and considering the PTR of the formulations, which is in highest count, is a logical and right decision. Therefore, NPPA has rightly considered the PTRs of Drez 10% solution (100ml) and Wokadine 10% solution (500ml), being on highest count.

5.2 However, some discrepancy is noticed in considering the PTR of Wokadine 10% solution (1000ml). On perusal of calculation sheet, it is noticed that the PTR of Wokadine 10% solution (1 ltr.) as well as of Wokadine 10% solution (100ml) is taken as Rs.81.52, which is illogical. Pharmatrac also confirmed that the formulation Wokadine 10% solution 1 Ltr. Pack is inactive and the price captured is of 100ml pack.

5.3 In view of the above, NPPA needs to be directed to re-fix and re-notify the ceiling price of formulation Povidone Iodine 10% solution by excluding the PTR of Wokadine 10% solution 1 ltr. pack, which is an inactive pack.

6. Decision:

“NPPA has rightly considered the PTRs of Drez 10% solution (100ml) and Wokadine 10% solution (500ml), being on highest count. However, NPPA is hereby directed to re-fix and re-notify the ceiling price of formulation Povidone Iodine 10% solution by excluding the PTR of Wokadine 10% solution 1 ltr. pack, (which is an inactive pack), within 30 days of the issue of this Order.”

Issued on this date, the 8th day of October, 2018.

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

Copy to:-

1. M/s Win-Medicare Pvt. Ltd., 1311, Modi Tower, 98, Nehru Place, New Delhi-110019.
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.