

**No. 31015/34/2017-Pricing
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 Win Medicare Pvt. Ltd. against price fixation of "Povidone Iodine Solution 10%" vide NPPA order No. S.O. 443(E), dated 14.02.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 06.03.2017
2) NPPA notification under review S.O. 443(E), dated 14.02.2017
3) Record Note of discussions held in the personal hearing held in the matter on 06.06.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Win Medicare Pvt. Ltd. (hereinafter called the petitioner) against notification S.O. No.443(E), dated 14.02.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Povidone Iodine Solution 10%

2. The petitioner has contended as under:-

Company has submitted that the said price fixation is incorrect and wrong for the following reasons:

(a) Ceiling price of every scheduled formulation is fixed/revised in accordance with provisions Para 4 of the DPCO, 2013. 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. The NPPA is bound to act within the four corners of the DPCO, 2013 and strictly follow the correct data base (in terms of the prices of the relevant period), however, the same admittedly has not been followed in the present case.

(b) The NPPA vide Official Memorandum dated 26.10.2016 uploaded the calculation sheets indicating proposed revision in the ceiling / retail price of various scheduled formulations and further directed that anyone aggrieved with the same shall approach the NPPA along with necessary documents as mentioned in the said order. Company vide letters dated 07.11.2016 and 09.11.2016 communicated to NPPA that inadvertently wrong and incorrect PTR/Price per unit of their 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 calculation sheet. However, despite providing all the relevant details including Form V, NPPA arbitrarily vide impugned notification being S.O. 443 (E) dated 14th February, 2017 wrongly fixed the ceiling price of Povidone Iodine Solution 10% at Rs. 0.66 for 1 ml wherein they have considered the PTR of our formulation as Rs. 163.81 whereas admittedly the correct PTR is Rs. 384.54. They also attached the photo of the said sample along with relevant Form V.

- (c) The NPPA while uploading the data in the said calculation 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/- (MRP Rs. 106.50), 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/-.
- (d) Company further submitted that It is pertinent to state that the prices / PTR mentioned in the said calculation sheet on the face of it shows that the same are incorrect and wrongly considered by NPPA. For Example, on one hand 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.
- (e) Therefore, it is most humbly requested that the notification being S.O. 443 (E) dated 14th February, 2017 be withdrawn and suitably amended qua our formulation. Company had addressed a letter to Sh. A.K. Khurana (Director Pricing) NPPA on 07.11.2016, interalia highlighting the following anomalies and infirmities in the Calculation Sheet published on the website of the NPPA:
 - (i) That for Betadine 10% Solution with pack size 500 ml, inadvertently and incorrectly wrong PTR i.e. Rs. 163.81 has been taken into consideration whereas the correct PTR being Rs. 384.54.
 - (ii) It was further brought to the notice of NPPA that price per unit of 'Betadine 10% Solution with pack size 500 ml has been taken as Rs. 0.33 whereas the correct price per unit is Rs. 0.76.
- (f) Further, Company had provided all the requisite information i.e. sample invoices to retailer of August 2015 along with Form V, as required under the Office Memorandum dated 26.10.2016 and Company also requested the concerned authority that the duly attested copies of the sample invoices in the prescribe format will be provided shortly. Since the compilation of the Invoices was time consuming (the same being voluminous in nature), our Company requested for a

short extension to submit the same. Our Company also highlighted various other infirmities / corrections in the said calculation sheet wherein NPPA has wrongly taken into account incorrect PTR / Price per unit for various other formulation manufactured by various other companies.

- (g) Subsequently on 09.11.2016 (after 2 days), Company addressed another letter to Sh. A.K. Khurana (Director Pricing) NPPA, whereby the duly attested sample invoices of Betadine 10% Solution with pack size 500 ml in the prescribed format were submitted as required under the Office Memorandum dated 26.10.2016. However, despite providing all the necessary details to NPPA to correct and modify the prices in the said calculation sheet, NPPA has failed to do so.
- (h) Subsequently on 02.03.2017, **Company addressed a letter to Pharma Trac interalia stating that the data (PTR and MRP) provided by their organization to NPPA basis which NPPA have revised the ceiling price of our formulation is incorrect and erroneous. It was further pointed out that not only Pharma Trac had provided the incorrect data pertaining to their formulation but also qua various other formulations in market which are using Povidone Iodine Solution 10% for manufacturing their formulation thereby causing grave prejudice to the Company.**
- (i) Pursuant to the aforementioned letter, Pharma Trac vide its letter dated 17.03.2017 (contents whereof are self-explanatory) acknowledged that the data (PTR and MRP) provided by their organisation to NPPA **pertaining to their 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. Company has also attached the copy of said letter.**
- (j) It is therefore clear from the above that the prices considered by NPPA while fixing the ceiling price of their formulation is incorrect and faulty and therefore the same is required to be amended.

2. In view of above, company requested that in view of the Review Petition filed by Company and the subsequent letter dated issued by the Pharma Trac, their Review Petition be accordingly decided at the earliest and the notification being S.O. 443 (E) dated 14th February, 2017 whereby the ceiling price of Povidone Iodine Solution 10% (their formulation being Betadine 10% Solution) was fixed on complete faulty and incorrect price be suitably rectified/amended. This entire incorrect exercise is causing grave prejudice to them.

3. Comments of NPPA:

The ceiling price of Rs. 0.66/ml for **Povidone Iodine 10% Solution** was notified vide S.O. 443(E) dated 14.02.2017 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

2. Company has stated that correct methodology was not followed in arriving at the ceiling price for **Povidone Iodine 10% Solution**. The points raised by the company are

not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has pointed out that ceiling price has not been worked out as per para 4 of DPCO, 2013.	NPPA has rightly fixed ceiling price of Rs.0.66/ml vide S.O. 443(E) dated 14.02.2017 for Povidone Iodine 10% Solution as per para 4 and considering the decision of 27 th Authority meeting held on 29 th May, 2016 in order to maintain the consistency and uniformity in price fixation exercise.
2.	<p>Company has point out that NPPA has considered PTR Rs. 163.81 for their product Betadine 10% Solution - 500ml against the actual PTR of 384.54. Company has also stated that PTR Rs. 33.15 is considered against the actual PTR Rs. 79.44 for Drez 10% So Pharmaceutical Pvt. Ltd. in the same way PTR Rs. 297.56 was considered against actual PTR Rs. 320.96 for Wokadine 10% Solution of M/s Wackhardt Limited.</p> <p>Company also submitted representation alongwith documents against O.M. no 8(35)/2016/DP/NPPA/Div.II 26.10.2016 but the same was not considered by NPPA.</p>	<p>Representation submitted by the company was examined by NPPA observations are as follows:-</p> <p>(a) Betadine 10% Solution 500ml - the detail was sent to pharma-trac via e-mail for verification pharma-trac confirmed the PTR submitted for August, 2015 was wrong and stated that correct PTR of this formulation for the month of August 2015 is Rs. 370.29.</p> <p>(b) Drez 10% Solution 100ml - The letter was written to M/s Stredman Pharma for submission the PTR of Drez 10% Solution 100ml. Company stated PTR Rs. 82.69 for Drez 10% Solution. The detail was sent to pharma-trac via e-mail for verification pharma-trac confirmed PTR Rs. 78.42 for subject formulation.</p> <p>(c) Wokadine 10% Solution 500ml- The detail submitted by the company was sent to pharma-trac via e-mail for verification. Pharma-trac confirmed existing the PTR.</p> <p>(d) Wokadine 10% Solution 1000ml - The detail was sent to pharma-trac for verification of the same. Pharma-trac confirmed that the product was replaced in the market and merged with Wokadine 10% Solution 100ml. The information submitted by phama-trac was put up before the Authority observed that the information submitted by the pharma-trac does not confirmed to company claim and IPDMS compliance of the companies was not 100% at that time that</p>

		therefore representation submitted by the company was not considered by the Authority.
3.	Company has also pointed out that PTR Rs. 81.52 is considered for Wokadine 10% Solution 100ml, Rs. 81.52 for 500ml and Rs. 81.52 for 1000ml Wokadine 10% Solution which shows price exercise process is purely mechanical.	NPPA has considered the PTR for different packs of Wokadine 10% Solution 100ml as per the data provided by pharma-trac for the month of August, 2015.

Company has not challenged any notification in respect of **Povidone Iodine 10% Solution** in the Court.

4. During the personal hearing, the representatives of the company further submitted that the basis for fixing the ceiling price fixed vide impugned notification No. SO 443(E) dated 14.2.2017 was the data provided by Pharmatrac (for the period August, 2015). However, while fixing the ceiling price, the incorrect data provided by Pharmatrac was considered by NPPA. The company had in this regard, addressed a letter on 2.3.2017 to Pharmatrac, inter alia, stating that incorrect prices were provided by their organization to NPPA basis which incorrect ceiling price has been fixed by the NPPA for the formulation (Povidone Iodine solution 10%) vide notification, dated 14.2.2017. The Pharmatrac vide its letter dated 17.3.2017 clarified the following –

- a. As far as the applicant's formulation is concerned, i.e. Betadine Solution 10% (pack size 500 ml), the Pharmatrac clarified in its said letter that incorrect PTR of Rs.163.81 was considered by NPPA while fixing the ceiling price, whereas the correct PTR as per Pharmatrac is Rs.370.29. It is hereby clarified that the correct PTR for the applicant's formulation is Rs.384.54 for which company has already supplied the copy of Form V, as well as copy of the invoices, as was required by NPPA. The said position has been accepted by the NPPA in their written submission.
- b. The Pharmatrac vide the said letter also clarified that the NPPA has wrongly considered the PTR for Drez 10% solution (pack size 100 ml) as Rs.33.15 whereas the correct PTR is Rs.78.42. The said position has been accepted by the NPPA in their written submission.
- c. As far as the PTR of Wokadine 10% solution (pack size 100 ml) is concerned, the price considered by NPPA as per their calculation sheet as well as the price provided by Pharmatrac is Rs.81.52. The PTR of Wokadine 10% solution (pack size 500 ml) as considered by NPPA is Rs.297.56. The PTR of Wokadine 10% solution (pack size 1000 ml) as considered by NPPA is Rs.81.52. In this regard, it is clarified that it is a matter of common parlance that if the size / quantity / volume of a product increases, the price is bound to increase and under no circumstances, the PTR of 100 ml pack will be equivalent to the PTR of 1000 ml pack. It is further submitted that the Pharmatrac in this regard has clarified in the said letter dated 17.3.2017 that the said product i.e. Wokadine 10% solution

(pack size 1000 ml) was not available in market during the relevant period, i.e. August, 2015, which has been wrongly considered by NPPA while fixing the ceiling price of the formulation in question. The said position has been accepted by the NPPA in their written submission.

Further, during the course of hearing, the representatives of NPPA referred to a new OM, in terms of which, the company is required to provide some information relating to the formulation in question. In this regard, it is submitted

- (i) The copy of the aforesaid, which was being referred by the representative of NPPA, was not handed over or placed during the hearing.
- (ii) The aforesaid OM must have come subsequent to filing of the present review application and, therefore, is not applicable.
- (iii) If at all directed, the company can provide the data pertaining to their formulation.

The aforesaid stand of the company will be clear from the table herein below:

Details of formulation and pack size	Price (PTR) wrongly considered by NPPA (during August, 2015) while fixing the ceiling price	Prices (PTR) (during August 2015) provided by Pharma Trac in their letter dated 17.3.2017	PTR (in August 2015) as stated in invoices / Form V submitted to NPPA by our company
Betadine 10% solution (500 ml)	163.81	370.29 / 384.54	384.54
Drez 10% solution (100 ml)	33.15	78.42	-----
Wokadine 10% solution (100 ml)	81.52	81.52	-----
Wokadine 10% solution (500 ml)	297.56	297.56	-----
Wokadine 10% solution (1000 ml)	81.52	Inactive	-----

In the light of the above, it is most humbly submitted that the impugned notification No. SO 443(E), dated 14.2.2017 be suitably rectified / amended for the formulation Povidone Iodine solution 10%.

NPPA representatives stated that the issue may be looked into on submission of relevant documents by the company.

5. Examination:

In the instant case, the company's contention is that NPPA has taken into account wrong and incorrect PTR/Price per unit of various formulations while fixing the ceiling price of the formulation Povidone Iodine 10% solution, as shown in the table

given at para 4 above. In support of their claim, the company also submitted a letter dated 17.3.2017 of AWACS during the personal hearing.

NPPA has also confirmed that on receipt of representation from the petitioner company, they got confirmation from Pharmatrac via e-mail for verification and Pharmatrac confirmed the actual PTR of various formulations for August, 2015. The PTR considered by NPPA in the calculation sheet and the actual price to be considered (and confirmed by Pharmatrac) are shown in the table given below:

<u>Details of formulation and pack size</u>	<u>PTR considered by NPPA while fixing the ceiling price</u>	<u>Actual PTR confirmed by Pharmatrac</u>
Betadine 10% solution (500 ml)	163.81	370.29
Drez 10% solution (100 ml)	33.15	78.42
Wokadine 10% solution (100 ml)	81.52	81.52
Wokadine 10% solution (500 ml)	297.56	297.56
Wokadine 10% solution (1000 ml)	81.52	Product replaced in market and merged with Wokadine 10% solution 100ml

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.

In view of the above, NPPA may be 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 excluding the PTR of Wokadine 10% solution 1000ml, having less than 1% market share.

6. Government Decision:

“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.”

Issued on this date, the 28th day of September, 2017.

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

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

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