

**No. 31015/20/2017-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 Wockhardt Limited against price fixation of "Povidine Iodine Solution 10% (Wokadine 10% Solution)" vide NPPA order No. S.O. 443(E), dated 14.2.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application dated 01.03.2017  
2) NPPA notification under review S.O. 443(E), dated 14.2.2017  
3) Record Note of discussions held in the personal hearing held in the matter on 04.07.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Wockhardt Limited (hereinafter called the petitioner) against notification S.O. No.443(E), dated 14.2.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Povidine Iodine Solution 10% (Wokadine 10% Solution)

2. The petitioner has contended as under:-

- I. In spite of representation and several submissions made to NPPA with regards to proposed ceiling price for Povidone Iodine 10% (summarized below), NPPA has announced ceiling price same as proposed ceiling price hence ignored their all representations and submissions.

Date	Subject	Submitted to	Reply Recd
26/10/2016	Working sheet uploaded by NPPA website for povidine Iodine Solution 5% and 10% as per NLEM 2015.		
08/11/2016	Representations against the proposed ceiling price for Povidone Iodine solution 10% uploaded on NPPA website dated 26 <sup>th</sup> October, 2016.	NPPA	NO
28/11/2016	PTR, MAT data with sample invoice provided to NPPA for the month of Aug-15 for Wokadine 10% 100 ML	NPPA	NO
07/02/2017	Declaration that all forms are submitted in IPDMS for all products.	NPPA	
14/02/2017	Ceiling price announced as per S.O. 443(E) Povidone Iodine Solution 10%.		

- II. The company's major concerns with respect to above stated notification are as under:
- (i) In case of liquid formulations, it is irrational and unscientific to calculate average price to retailer on dosage basis. A 100 ML bottle pack cannot be equated with 1000 ML bottle pack for averaging purpose. Cost of packaging and conversion cost per ML are much higher in case of smaller packs. This is resulting in major drop in prices of smaller packs which contribute more than 85% of overall sales. Due to further drop in prices, company is incurring losses which in turn now raised a question on viability to sell the said formulations.
  - (ii) Larger packs are mostly for hospital supply and priced much lower than common packs. These packs therefore should not be considered for arriving at average price to retailer for most commonly used packs.
  - (iii) Average retail price considered for Povidine Iodine 10% solution with market share more than 1% includes our company product Wokadine 1000ML. **They informed that the last batch manufactured for said pack size was in year 2012. As the expiry for Wokadine 1000 ML is twenty four months, hence it is very unlikely that said formulation would have been sold in year 2014-2015. Also the average PTR per pack considered for 100 ML and 1000 ML is same as Rs.81.52/- which is incorrect.**
  - (iv) In the working sheet, manual adjustment in average price is made for few packs. For example in BETADINE 10 % SOLUTION 50 ML price per unit is showing as Rs. 1.28/- however in column price per unit considered is Rs. 0.87/-
  - (v) Company further submitted that in case of review application filed by M/s. Sun Pharmaceuticals Industries Ltd. against fixation of ceiling price of "Ciprofloxacin 500 mg tablet" DOP order number 31015/40/2015-PI.I dated 29<sup>th</sup> November, 2016. Government decision pronounced that "NPPA is directed to adopt the correct methodology in all such cases of calculating the ceiling price of scheduled formulations as per para 4(i) of DPCO, 2013 and provisions of existing Schedule-I by **including market shares of only generic / brands and not company-wise MAT percentage** and to re-fix the ceiling prices of the Ciprofloxacin 500 mg. and Ciprofloxacin 250 mg. tablets, on merit, after due verification of all data within a period of one month from the date of issue of the Order". Same case if applicable in case of Povidone Iodine 10% where NPPA have derived the ceiling price based on company wise MAT value.
- III. In view of above, company requested this Department to direct NPPA for the withdrawal of the notification related to above formulation and re-fix the ceiling price.

3. Comments of NPPA:

- I. Ceiling price of Povidone Iodine Solution 10% was notified as Rs. 0.66/ml vide S.O. 443(E) dated 14.02.2017 and revised to Rs. 0.67/ml vide S.O.

1039(E) dated 01.4.2017 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

- II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Povidine Iodine Solution 10%**. 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.	<p>Company has stated that it is irrational and unscientific to calculate average price to retailer on dosage base. A 100ml bottle pack cannot be equated with 1000ml bottle pack for average purpose.</p> <p>Larger packs are mostly for hospital supply and priced much lower than common packs. These packs therefore, should not be considered for arriving ceiling price.</p>	<p>DPCO does not differentiate between 100ml &amp; 1000ml pack. NPPA has consistently followed uniform practice for price fixation of scheduled formulations under DPCO 2013 and the same was upheld by DoP (refer review order no. 31015/31/2013-PI.I dated 23.12.2013 in respect of Povidine Iodine Solution 5% and S.O. 1905(E) dated 28.6.2013 wherein DoP stated that DPCO, 2013 does not distinguish between sales through retailers shop or through hospital outlets.</p>
2.	<p>NPPA has considered their product Wokadine 1000 ml for driving the ceiling price while they have discontinued to manufacture/market in 2012.</p>	<p>NPPA considered the data provided by AIOCD-AWACS for the month of August, 2015.</p>
3.	<p>In working sheet manual adjustment in average price is made for Betadine 10% solution.</p>	<p>Povidine Iodine 10% solution was included in NLEM 2011 also. Therefore, no adjustment is made in average price but average price is restricted based on the prevailing ceiling price.</p>
4.	<p>Company has requested to fixed the ceiling price as per para 4 (1) of DPCO, 2013 in line with review order 31015/40/2015-PI.I dated 29.11.2016</p>	<p>NPPA has been consistently following the policy of taking the least of the three alternatives while fixing the ceiling price under NLEM 2015 based on the decision of 27<sup>th</sup> Authority meeting held on 29.03.2016.</p>
		<p><b>Detail of trade margin based on AIOCD-AWACS data as on August 2015:-</b>            Trade Margin from PTS level            Povidone Iodine 10%            500ml solution - 88.81%            100ml Solution - 36.73%</p>

		1000ml Solution – 36.73%
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III. Company has not challenged any notification in respect of **Povidine Iodine Solution 10%** in the Court.

4. During the personal hearing, in addition to written submissions already made, the representatives of the company further submitted that the trade margin in case of Wockadine 100ml solution is 25% on PTR as per the industrial practice whereas for other packs, i.e. 500ml, the company is giving higher margin.

NPPA representative submitted that the price of **Povidine Iodine Solution 10%** has been fixed as per existing provisions of DPCO, 2013.

NPPA representative submitted that they may examine the issue regarding discontinuation of 1ltr. Pack on submission of relevant documents by the company.

## 5. **Examination:**

The contention of the petitioner company that 1000ml pack, which is an hospital pack, should not be considered, based on its pack size, it is stated that DPCO, 2013 does not distinguish between sales through retailers shop or through hospitals due to pack size. Para 11(1) and 11(2) provides that the average price to retailer shall be on the dosage basis, (per tablet, per capsule or injection in volume as listed in first schedule) and the ceiling price or retail price of pack shall be reached by multiplying the same with the number of quantity in the pack, as the case may be. In the event of the unit of the dosage for a scheduled formulation not available in the first schedule, the lowest pack size for that category of medicine, as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder, shall be taken as unit dosage for calculating the ceiling price for that scheduled formulation. **Otherwise also, the market share of Wokadine 10% solution 1000ml pack of the company is less than 1% and automatically excluded for consideration for averaging purpose under para 4 of DPCO, 2013.**

5.2 However, regarding the contention of the petitioner company about the criteria for fixing ceiling price of the subject formulation by considering only those brands having more than 1% market share, on examination, it is found that NPPA has erred in calculating ceiling price as per para 4 of DPCO, 2013, which reads as under :-

### ***“4. Calculation of ceiling price of a scheduled formulation***

*(1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the First Schedule shall be calculated as under:-*

**Step 1:** *First the Average price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:-*

**Average Price to Retail P(s) =** *(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).”*

5.3 The DPCO does not recognise a company for average PTR but only medicines/formulations. Thus, only those formulations are to be considered, which are having MAT value of more than 1% market share. On going through the calculation sheet of the formulation, it is observed that the number of formulations which are to be considered having more than 1% market share and number of formulations to be excluded, as per table given below:-

<u>Formulation name</u>	<u>Number of brands to be considered having more than 1% market share</u>	<u>Number of brands to be excluded</u>
<b>Povidine Iodine Solution 10%</b>	07	02

5.4 In view of the above, NPPA may be directed to refix the ceiling price of the formulation by considering only those medicines / formulations having MAT value of more than 1% market share, as DPCO does not recognise a company for average PTR but only medicines / formulations.

**6. Government Decision:**

**“The grievance of the company that price of 100ml pack cannot be equated with 1000ml pack for averaging purposes on the ground that the cost of packaging and conversion cost per ml is much higher in case of smaller pack cannot be considered since para 11(1&2) of DPCO, 2013 DPCO, 2013 does not distinguish between sales through retailers shop or through hospitals due to pack size.”**

**“NPPA is, however, directed to refix the ceiling prices of the formulation Povidine Iodine Solution 10% (Wokadine 10% Solution) by considering only those medicines / formulations having MAT value of more than 1% market share, as DPCO does not recognise a company for average PTR but only medicines / formulations.”**

Issued on this date, the 28<sup>th</sup> day of September, 2017.

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

To

1. M/s. Wockhardt Limited,  
Wockhardt Towers,  
Bandra Kundra Complex,  
MUMBAI-400 051.

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