

No. 31015/98/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

**A- Wing, Shastri Bhawan,
New Delhi 110 001**

Subject: Review application of M/s Wockhardt Limited against price fixation of "Povidone Iodine Solution 5% (Wokadine 5% Solution)" vide NPPA order No. S.O. 3431(E), dated 10.11.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 22.11.2016
2) NPPA notification under review S.O. 3431(E), dated 10.11.2016
3) Record Note of discussions held in the personal hearing held in the matter on 03.01.2017.

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.3431(E), dated 10.11.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Povidone Iodine Solution 5% (Wokadine 5% Solution)

2. The petitioner has contended 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.
- 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. As per Para 4 of DPCO, 2013 for calculation of ceiling price of a scheduled formulation, average Price to Retailer shall be calculated as : " (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.)". It is clear from the formula definition that average price to retailer which is reflected in considered data base having more than 1% market share would be considered as it is. However it is seen in the working sheet that manual adjustment in average price is made for few packs. For example in Povidone iodine 5%

BETADINE 5 % SOLUTION 100 ML price per unit is showing as Rs. 0.81/- however in column price per unit considered is Rs. 0.37/-.

- IV. They requested this Department to direct NPPA for withdraw of the notification related to above formulations and re-fix the ceiling price.

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 0.39/ml vide S.O. 1651(E) dated 14.6.2013 and the same was revised to Rs. 0.41, Rs. 0.43 & 0.42 per ml vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011 and Rs. 0.33/ml vide S.O. 3431(E) dated 10.11.2016 under NLEM 2015.
- (ii) DPCO, 2013 does not differentiate between small volume and large volume pack size. DoP vide review order no 31015/35/2013-PI.I dated 11.10.2013 had also accepted the price fixation exercise followed by NPPA in the subject formulation in the review petition filed by M/s Win Medicare Pvt. Ltd. against S.O. 1651(E) dated 14.6.2013.
- (iii) The request of company to withdraw S.O. 3431(E) dated 10.11.2016 in respect of **Povidone Iodine Solution 5%** is not acceptable.
- (iv) NPPA has fixed the ceiling price for this formulation as per para 4 of DPCO, 2013. PTR of 5% Betadine Solution is restricted to the then prevailing ceiling price.
- (v) Company has submitted objection on draft working sheet but the same was rejected being time barred.
- (vi) As per information available with NPPA company has challenged S.O. 1651 (E) dated 14.6.2013 in respect of Povidone Iodine Solution 5% in Bombay High Court vide WP No. 2201/2014 decision is pending.

3. During the personal hearing, in addition to written submissions already made, the representatives of the company further submitted that correct methodology in calculating the ceiling price has not been followed by including market share of generic / brands having less than 1% market share, e.g.

Povidone Iodine (Wockhardt)	MAT%	0.14
PVPI (Wockhardt)	MAT%	0.18
Betaseptic (Win Medicare)	MAT%	0.07
Betaseptic (Win Medicare)	MAT%	0.23.

The representatives of the company confirmed that they are following the ceiling price notified by NPPA and also submitted copy of Form-V.

4. NPPA representative submitted that the issue regarding inclusion/non-inclusion of generic / brand having less than 1% market share is based on the least of the three alternatives decided by the Authority in its 27th meeting.

5. Examination:

The petitioner company has challenged the NPPA Order S.O. 3431(E) dated 10.11.2016 for price fixation of their formulation **Povidone Iodine Solution 5% (Wokadine 5% Solution)**. The main contention of the petitioner company is that to calculate average price to retailer on dose basis, 100ml bottle pack cannot be equated with 1000ml bottle pack for averaging purpose. The company in the review application stated that the cost of packaging and conversion cost per ml are much higher in case of smaller packs. As per DPCO, 2013, the basis while fixing the ceiling price has moved to market based data and considering cost based data is uncalled for. Moreover, since there is no added therapeutic advantage mentioned by the company, separate ceiling price cannot be considered based on pack size under para 11(3) of DPCO 2013.

As regards the second grievance, as per para 4(i) of DPCO, 2013, 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 is to be considered for fixing the ceiling price. The DPCO does not recognise a company for average PTR but only medicines / formulations. Thus, only 5 formulations are to be considered having MAT value of more than 1% each instead of 12 considered by NPPA in its calculation. Regarding the price per unit of Povidone iodine 5% Betadine 5% solution 100 ml, it is seen from the calculation sheet that the price per unit as per August, 2015 data is Rs.0.81. However, NPPA has considered the price as Rs.0.37/per unit. On examination, it is found that the ceiling price of the formulation was fixed as Rs.0.42/ml (including 16% retailer margin) for Povidone Iodine Solution 5% vide SO 644(E), dated 2nd March, 2016 (S.No.424). Based on this, the NPPA has rightly restricted the price to Rs.0.37/ml. It is also observed that the prices of the formulation of other companies are between 0.18 to Rs.0.35 per unit. Hence, the grievance of the company has got no merit.

6. Government Decision:

“The grievance of the company that price of 100ml bottle pack cannot be equated with 1000ml bottle pack for averaging purpose on the ground that the cost of packaging and conversion cost per ml is much higher in case of smaller packs cannot be considered since in DPCO, 2013, the basis while fixing the ceiling price is market based data and not cost based data. Moreover, there is no added therapeutic advantage of smaller pack mentioned by the company. Therefore, the grievance of the company cannot be accepted.

The grievance that NPPA has considered the price of Rs.0.37/unit for Povidone iodine 5% Betadine 5% solution 100 ml. instead of Rs.0.81/unit has also got no merit, as NPPA has rightly restricted the price at Rs.0.37/ml, based on ceiling price fixed vide SO 644(E), dated 2.3.2016.

However, NPPA is directed to re-fix the ceiling price of Povidone Iodine Solution 5% (Wokadine 5% Solution) in accordance with the provisions of DPCO by considering the PTR of 5 formulations only having more than 1% market share, as the DPCO does not recognise a company for average PTR but only medicines / formulations.”

Issued on this date, the 5th day of April, 2017.

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

To

1. M/s. Wockhardt Limited
Wockhardt Towers,
Bandra Kurla Complex,
Mumbai-400051.
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