

No. 31015/15/2017-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 a review application dated 02.02.2017 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Cadila Healthcare Limited (hereinafter called the applicant) against notification S.O. No.248(E), dated 24.01.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulation Dexamethasone Injection pack of 2ml (strength 4mg/ml).

2. The applicant has contended as under:

2.1 Ceiling price notification for Dexamethasone injection (4mg/ml) was notified by NPPA on 28.04.2014 under DPCO, 2013 (NLEM 2011). While averaging the prices National Pharmaceutical Pricing Authority (NPPA) had erred by notifying the price on per ml basis for various packs namely 2ml, 10ml and 20ml.

2.2 While notifying the prices on per ml basis for such Small Volume Parenteral (SVP) NPPA notified ceiling prices were erroneous. Price for retail pack of 2 ml was abnormally low while that of multidose packs of 10ml & 20ml were abnormally high.

2.3 NPPA took its time to constitute the committee of experts under para 11(4). Constitution of this committee of experts was never notified by NPPA. However Minutes of 3rd meeting of this committee held on 28.12.2016 were made public on 12.01.2017. While going through the minutes, it is understood that the said committee recommended for ceiling prices on pack wise basis rather than per ml basis. Minutes of the said meeting does not state if the committee was apprised of the anomaly of abnormally low price for retail pack of 2ml and the difficulty being faced by the applicant in making the continuous and uninterrupted supply of 2ml pack since 28.04.2014.

2.4 Applicant welcomed the decision of the expert committee for pack wise ceiling prices for Dexamethasone Injection 4mg/ml. In light of the recommendation of expert committee, NPPA in its Authority meeting held on 23.01.2017 decided to notify the ceiling prices on pack wise basis and thus partially corrected the anomaly of abnormally low price of retail pack of 2ml.

2.5 Ceiling price order no. S.O. 248(E) dated 24.01.2017 issued by NPPA:

They found that the price fixed by NPPA for schedule formulation Dexamethasone Injection 4mg/ml pack of 2ml vide ceiling price order no. S.O 248(E) dated 24.01.2017 at sr. no. 5 of the order is not correct. The details of the price fixed vide above referred order for Dexamethasone injection pack of 2ml is as below:

Sr. No.	Name of the Schedule Formulation	Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
5	Dexamethasone Injection	Dexamethasone 4mg/ml	Each pack (2ml)	5.28

2.6 The applicant submitted that the recent ceiling price notified as above is Rs.5.28/2ml while the ceiling price notified on 20.08.2014 was Rs. 5.34/2ml as per order no S.O. 2095(E). It is also important to note the ceiling price notified under DPCO 1995 for 2ml was Rs. 7.72/2ml as per order no. S.O. 1506 (E) dated 01/07/2011.

2.7 This highlights that the anomaly of abnormally low ceiling price has been further aggravated by the latest notification no. S.O. 248(E) dated 24/01/2017. NPPA has failed to appreciate their concern and has ignored the interest of long term sustained availability of Dexamethasone 2ml Injection in the larger interest of the Indian patients.

2.8 NPPA has taken market data of August 2015 as the base price which is not the right base price. While notifying the price on 28.08.2014 NPPA had taken market data of September 2013 prices as the base price. Therefore to correct the anomaly NPPA should take market data of September 2013 as the base price coupled with subsequent WPI for subsequent years. This will correct the anomaly and will give a correct ceiling price to ensure the continuous and sustained supply of Dexamethasone 2ml Injection.

2.9 The correct calculation based on market data of September 2013 along with effect of WPI for subsequent years is given as below:

<b>Dexamethasone Injection 4mg/ml in pack of 2ml</b>	
Sum of MAT value considered for price calculation (Rs. In Lakhs)	63,37.92
Sum of PTR per unit considered for price calculation	25.68
Number of Packs considered	4
Average PTR	6.42
Add : 16% Retailer Margin	1.03
Ceiling price (without local taxes)	7.45
Ceiling price with effect of WPI	8.00

The above table shows that there is a gross error in the notified price of Rs.5.28/2ml as notified on 24.01.2017.

Submission:

- (a) Ceiling Price for Dexamethasone Injection 2ml pack (4mg/ml) should be reworked by NPPA based on market data of September 2013 and give effect of addition or subtraction of positive or negative WPI for the subsequent years. This will give fair and equitable price for Dexamethasone Injection 2ml pack (4mg/ml).
- (b) NPPA may also be directed to develop a Standard Operating Procedure (SOPs) for disposing of the representations filed against the Draft working sheets or the Notification(s).

They submitted that they have implemented the notified price of Dexamethasone Injection 4mg/ml pack of 2ml.

- I. In view of above facts, they requested this Department to consider the above facts favorably and direct the NPPA to re-notify the ceiling price for Dexamethasone Injection 2ml pack (4mg/ml).

3. Comments of NPPA:

- I. In this regard, it is mentioned that ceiling price of Rs. 5.28 per Pack (2ml) for Dexamethasone 4mg/ml Injection was notified vide S.O. 248(E) dated 24.01.2017 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.
- II. Applicant has stated that correct methodology was not followed in arriving at the ceiling price for Dexamethasone 4mg/ml Injection pack of 2ml. The points raised by the applicant are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013 and as per the decisions of 27<sup>th</sup> Authority meeting held on 29.3.2016. Details are as follows:-

Applicant's Grievances	NPPA's comments
<p>Applicant has pointed out that NPPA has notified prices per ml bases for injectable formulation resulted the manufacturing of Small Volume Parenteral (SVP) uneconomical. In spite of introducing of para 11(3 &amp;4) vide order 1192(E) dated 22.3.2016 significant increase in the ceiling price was not workout based on the recommendation of 3<sup>rd</sup> meeting of Expert Committee held on 28.12.2016. Applicant has requested to consider market data for the period of September 2013 instead of August 2015 for computation of Ceiling Price Dexamethasone 4mg/ml Injection pack of 2ml.</p>	<p>NPPA has fixed the ceiling price for Dexamethasone 4mg/ml Injection pack of 2ml as per the recommendation of the Expert Committee constituted by the NPPA for fixation the ceiling price under para 11(3&amp;4). Issue raised by applicant from Sl. No. 9 to 17 has no merit as per provision of DPCO, 2013.</p> <p>NPPA has considered the market data for the period of August 2015 under NLEM, 2015, as per Para 9(5) of DPCO 2013. Applicant's request is not admissible as per the provisions of DPCO, 2013.</p>

4. Examination:

The ceiling price of formulation Dexamethasone Injection pack of 2ml (strength 4mg/ml) has been fixed by NPPA vide SO 248(E), dated 24.1.2017 on the basis of recommendation of Expert Committee under para 11(3&4) of DPCO, 2013. The ceiling prices were fixed by considering August, 2015 data as per provisions in para 9(5) of DPCO, 2013.

4.2 The injectable fluids were in NLEM, 2011 and the ceiling price was already in existence for them, when the NLEM was revised in 2016. After revision of Schedule I of DPCO, due to revision in NLEM, the price caps of injectable fluids were re-fixed, this time, by segregating the pack sizes on the basis of recommendation of Expert Committee. Since while fixing the ceiling price of subject formulation on 28.04.2014, the

segregation of market based data on the basis of pack size was not done, this resulted in depressing the prices of smaller pack sizes. This lower base was taken while fixing the ceiling price of 2ml pack again on 24.1.2017, which resulted in further depressing the ceiling price of 2ml pack.

4.3 There is a merit in contention of the applicant that in peculiar circumstances of the case, use of market data of August, 2015 while re-fixing the ceiling price of the subject formulation has led to an anomalous situation whereby the price of the subject formulation has depressed unreasonably. This anomalous situation needs to be rectified in the interest of the long term sustained availability of Dexamethasone 2ml injection in the market. This could be justifiably rectified if the segregated market data of September, 2013 is used to arrive at a ceiling price along with giving effect to WPI for subsequent years.

5. Order:

NPPA is hereby directed to re-fix the ceiling price of Dexamethasone Injection 2ml pack (strength 4mg/ml) by considering September, 2013 market based data instead of that of August, 2015 and apply the WPI for the subsequent years.

Issued on this date of 10<sup>th</sup> day of January, 2019.

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

Copy to :-

1. M/s. Cadila Healthcare Limited, Zydus Tower, Satellite Cross Road, Ahmedabad-380015.
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