

No. 31015/16/2017-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,  
New Delhi 110 001

Order

This is an order on a review application dated 31.01.2017 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Wockhardt 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 Revised ceiling price for Dexamethasone 4mg/ml was announced on 24<sup>th</sup> January,2017 as per S.O.248(E). Various representations were submitted on issuing requisite directive to NPPA for re-fixing the ceiling price in supersession of order no S.O. 1157 (E) dated 28th April, 2014. NPPA has issued S.O.248(E) based on August-2015 PTR which is based on S.O. 1157 (E). Below is the summary of representations made by the applicant for said formulations in the last two years:

Date	Subject	Submitted to	Reply received
06.05.2014	Withdrawal of notification S.O. 1157 ( E ) related to injections	DOP and NPPA	No
22.04.2016	Reworking of the ceiling price calculation for S.O.No.1157 ( E ) dated 28.04.2014 in pursuant to Para 11 (3) amendment vide Gazette notification S.O. 1192(3) dated 22.03.2016	DOP and NPPA	No
25.08.2016	Representation in respect of department OM no. 8(34)/2016/DP/NPPA/Div.II dated 12th August, 2016 in respect of the formulation of dexamethasone injection (Decdan) and Gentamycin injection (Magenta)	DOP and NPPA	No

2.2 Though NPPA has fixed separate ceiling prices for different packs of Injection in line with S.O. no 1192 (E) dated 22nd March, 2016, it has totally ignored various representation made by the applicant and other manufacturers for this formulation for re-fixing ceiling price in supersession of earlier order no S.O. 1157 (E) dated 28<sup>th</sup> April, 2014. This has resulted in further reduction of retail price of their formulations.

2.3 MAT value of September, 2013 should have been considered for re-fixing the ceiling price as against MAT value based on August, 2015 data. Considering the base price for August 2015 is itself incorrect as it was derived considering average of all packs.

2.4 Retail prices were further slashed as the PTR considered by NPPA for deriving ceiling price varies from the actual PTR calculation as per prevailing business practices of Pharma Industry. NPPA considers retailer margin as 16% on PTR whereas the industry works at a minimum threshold of 25% margin (on PTR). Hence, applicant requested to allow minimum 25% margin on PTR for arriving at ceiling prices.

2.5 Ceiling price notified as per price notification no S.O. no 1157 (E) dated 28.04.2014 had resulted in drastic reduction in prices of 2ml packs by more than 40% as ceiling price were fixed considering average prices of different packs taken together. Due to above reason, there is overall reductions in the Dexamethasone formulations in the market and many companies already stopped marketing the product. They ensured that formulations be available to consumer this can be well explained with the increase in market share from 23% in year 2013 to 68% in year 2015. They submitted that in the event if the prices are not corrected, they as a manufacturer of vitally important formulations of Decdan would have no alternative but to discontinue the same.

2.6 Though the aforesaid price fixation is arbitrary and compelling us to incur huge losses, they have in letter and spirit implemented the same.

2.7 The applicant requested this Department to issue requisite directive/clarification to NPPA in this regard so as to re-fix the ceiling prices fixed vide Price Fixation Notification S.O. 248(E) dated 24.01.2017 in respect of 2ml pack based on the MAT value as on September 2013 after factoring WPI movement for year 2014, 2015 and 2016.

3. Comments of NPPA:

3.1 Ceiling price of Rs.5.28/Pack (2ml) for Dexamethasone 4mg/ml each 2ml pack 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.

3.2 Applicant has stated that correct methodology was not followed in arriving at the ceiling price for Dexamethasone 4mg/ml each 2ml pack Injection. The points raised by the applicant are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Applicant's Grievances	NPPA's comments
Applicant has pointed out that they have submitted three representations to NPPA / DoP for re-fixing the ceiling price of Dexamethasone 4mg/ml each 2ml pack Injection. Details are as follows: - (1) Withdrawal of notification S.O. 1157(E) dated 28.4.2014 related to injection on the following ground –	NPPA had examined the representation submitted by applicant and found that the representation had no merit, therefore, the same was not considered. Reference is invited to review order no. 31015/25/2014-PI.I dated 07.07.2013 wherein DoP had stated, "procedure followed by NPPA is in line with provisions of DPCO, 2013".

<p>(a) Ceiling price had been derived on per ML base against the existing pack size base (2ml, 10ml, 20ml &amp; 30ml pack).</p> <p>(b) PTR of Small Volume Parental (SVP) /retail pack had been clubbed with Large Volume Parental (LVP) /hospital/dispensing pack for deriving the ceiling price. Averaging prices of deferent pack to derived ceiling prices for all packs are illogical, irrational &amp; unscientific. Applicant has requested separate ceiling price for different packs.</p> <p>(2) Reworking of the ceiling price calculation for S.O. 1157(E) dated 28.4.2014 in pursuant to Para 11(3) amendment vides Gazette notification S.O. 1192(E) dated 22.3.2016.</p> <p>(3) Representation in respect of Department OM no. 8(34)/2016/DP/NPPA/Div.II dated 12.8.2016 in respect of price fixation of Dexamethasone 4mg/ml each 2ml pack Injection.</p>	<p>There was no provision for separate ceiling price for different packs before the existence of notification S.O. 1192(E) dated 23.3.2016.</p> <p>NPPA had fixed separate ceiling price of Rs. 5.28/2ml pack, in the light of para 11(3) amendment vide Gazette notification S.O. 1192(E) dated 22.3.2016.</p> <p>Applicant submitted their representation dated 12.8.2016 and requested NPPA to consider the PTR and MAT value for the month of September, 2013 which is not acceptable. NPPA had rightly considered the PTR and MAT value for the month of August 2015 considering para 9(5) of DPCO, 2013.</p>
<p>Applicant has requested for a separate ceiling price for deferent packs of injection in line with S.O. 1192(E) dated 27.3.2016.</p>	<p>NPPA had fixed separate ceiling price for deferent packs of injection in line with S.O. 1192(E) dated 27.3.2016.</p>
<p>Applicant has asked to re-fix the ceiling price considering the data for month of September 2013, along with the impact of WPI.</p>	<p>Applicant request is not acceptable as the request for considering September, 2013 data under NLEM 2015 is not as per provisions of DPCO, 2013.</p>
<p>Applicant has requested to allow 25% retailer margin on PTR against the existing 16% retailer margin.</p>	<p>Applicant request is not as per the provision of DPCO, 2013.</p>
<p>Applicant has stated that MRP of subject formulation in 2ml pack has been reduced more than 40%.</p>	<p>Reduction may be on account of shifting of cost based pricing methodology to market based pricing methodology. Subject formulation under reference was a scheduled formulation under DPCO, 1995, as well as under NLEM 2011 &amp; 2015.</p>

#### 4. Examination:

The ceiling price of formulation Dexamethasone Injection pack of 4mg/ml each 2ml has been fixed by NPPA on the basis of recommendation of Expert Committee

under para 11(3&4) of DPCO, 2013. However, while doing this, as per provisions of para 9(5) of DPCO, 2013, the data of August, 2015 was considered.

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 applying 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. Wockhardt Limited, Wockhardt Towers, Bandra Kurla Complex, Mumbai-400051.
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