

No. 31015/25/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s Cadila Healthcare Limited against price fixation of their formulation "Methylprednisolone 40mg Injection" vide NPPA order No. S.O. 248(E), dated 24.01.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 02.02.2017
2) NPPA notification under review S.O. No.248(E), dated 24.01.2017
3) Record Note of discussions held in the personal hearing on 16.5.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Cadila Healthcare Limited (hereinafter called the petitioner) 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 Methylprednisolone 40mg Injection.

2. The petitioner has contended as under:

I. The price fixed by NPPA for schedule formulation Methylprednisolone 40mg Injection vide ceiling price order no. S.O. 248(E) dated 24.01.2017 at sr. no. 22 of the order is not correct. The details of the price fixed vide above referred order for Methylprednisolone 40mg Injection is as below:-

Sr. No.	Name of the Schedule Formulation	Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
22	Methylprednisolone Injection	Methylprednisolone - 40mg/ml	1ml	44.53

II. Working sheet for Methylprednisolone Injection

The working sheet of Methylprednisolone Injection placed on NPPA's website for calculation of ceiling price has anomaly that ceiling prices fixed and notified by NPPA for Methylprednisolone Injection vide notification no. 248(E) on 24.01.2017 is based on per ml average and includes various packs of differing sizes (1ml, 2ml, 5ml). Considering per ml price of 2 ml and 5 ml together for one pack of 40mg in powder is not correct. It can also be seen from the working sheet that there is an anomaly in PTR for 5ml pack and 1ml pack at sr. 8 and 9 i.e. Rs.50.29 for 5ml and Rs. 57.33 per 1ml of same brand, the PTR of 5ml pack is lower than that of 1ml pack.

III. Calculation of ceiling price

Below given is the summary of the ceiling price of Methylprednisolone Injection as per working sheet placed on NPPA's website.

Methylprednisolone Injection	
Sum of MAT value considered for price calculation (Rs. In Lakhs)	4493.43
Sum of PTR per unit considered for price calculation	276.24
Number of Packs considered	7
Average PTR	39.46
Add : 16% Retailer Margin	6.31
Ceiling price (without local taxes)	45.77
Ceiling price (with WPI effect)	44.53

The revised correct calculation of ceiling price for Methylprednisolone Injection considering correct data as per the working is as below;

Methylprednisolone Injection	
Sum of MAT value considered for price calculation (Rs. In Lakhs)	1668.33
Sum of PTR per unit considered for price calculation	307.41
Number of Packs considered	5
Average PTR	61.48
Add : 16% Retailer Margin	9.84
Ceiling price (without local taxes)	71.32

IV. The company submitted that there is gross error in the working sheet of Methylprednisolone Injection. Moreover, the pack of their product Depotex 40 Injection is in powder form and as per license the composition is "Each vial contains: Methylprednisolone Sodium Succinate USP equivalent to Methylprednisolone 40mg."

V. In view of above, company prayed as under:

- (i) Ceiling Price for Methylprednisolone Injection should be reworked by NPPA considering the correct pack and notify the separate price for liquid injection as well as powder injection.
- (iii) To consider the above facts favorably and direct the NPPA to re-notify the ceiling price for Methylprednisolone 40mg Injection.

3. Comments of NPPA:

- I. Ceiling price of Rs. 44.53 per ml for Methylprednisole 40mg/ml Injection was notified vide S.O. 248(E) dated 24.01.2017 as per para 4, 10, 11, 14, 16, 17 & 18 under DPCO 2013.
- II. Company has stated that correct methodology was not followed in arriving at the ceiling price for Methylprednisole 40mg/ml Injection. The points raised by the

company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013 and as per the decisions of 27th Authority meeting held on 29.3.2016. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has stated that NPPA has clubbed PTR of 1ml, 2ml & 5ml pack size to derive the average PTR for Methylprednisole 40mg/ml Injection. Company has also pointed out that considering per ml price of 2ml & 5ml together for 1 pack of 40mg in powder is not correct. NPPA has considered PTR Rs. 50.29 for 5ml pack and Rs. 57.33 for 1ml Pack of M/s Pfizer Ltd.	NPPA has considered PTR for Methylprednisole 40mg/ml Injection as per data provided by pharma-trac for the month of August, 2015 and fixed the ceiling price Rs. 44.53/ml as per the provisions of DPCO, 2013. NPPA has included Depotex 40mg Injection as the strength of Injection is 40mg/ml as mentioned in NLEM 2015. NLEM 2015 has no differentiation between injection and powder for injection with regard to Methylprednisole 40mg/ml Injection. NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. M/s Cadila Healthcare Pvt. Ltd. <u>did not make</u> any representation against the proposed retail price uploaded on NPPA's website.

III. Company has not challenged any notification in respect of Methylprednisole 40mg/ml Injection in the Court.

4. During the personal hearing, the company further submitted that :-

- NPPA Notified the Ceiling Price for Methylprednisolone 40mg/ml Injection vide Notification No. S.O. No. 248(E) dated 24.1.2017. The Ceiling Price notified is Rs.44.53 per ml. NPPA has considered 7 packs while arriving at the above Ceiling Price.
- While computing the price for Methylprednisolone 40mg/ml Injection, NPPA has relied on the August 2015 data of AWACS. This data is inaccurate and incorrect. This needs revalidation.
- The inaccuracy has crept in NPPA data on account of the following :
 - (a) NPPA has notified the Ceiling Price on per ml basis. It has ignored that Small Volume Parenterals (SVPs) are required to be considered for calculating Ceiling Price on pack wise basis. This is as per the DoP's S.O. No. 1192(E) dated 22.3.2016.

- (b) In the instant case, NPPA has considered 3 packs of Depo Medrol of Pfizer Limited having pack size of 1ml, 2ml and 5ml. Depo Medrol is Methylprednisolone Acetate Suspension for Injection.
 - (c) NPPA has considered one more pack of Pfizer Limited namely Solu Medrol 1ml. Solu Medrol is Methylprednisolone Sodium Succinate Injection. Moreover, Solu Medrol is a sterile powder.
 - (d) NPPA has also considered 2 packs of Depopred Injection of Sun Pharma Laboratories Ltd in packs of 1ml and 2ml. Depopred is Methylprednisolone Acetate Suspension for Injection.
 - (e) 1 more pack of Sun Pharma Laboratories Ltd is considered namely Ivepred Injection 1ml. Ivepred is Methylprednisolone Sodium Succinate Injection in a sterile powder for injection.
 - (f) From above it is clear that Methylprednisolone Injection is available as Suspension for Injection in 1ml, 2ml and 5ml packs. While it is also available as Sterile Powder Injection in 1ml pack.
 - (g) NPPA has erred in understanding and appreciating the difference between an injection in suspension form and in sterile powder form. Both are different. The therapeutic advantage of Methylprednisolone Sodium Succinate Powder for Injection is that it is soluble in water and may administered in a small volume of diluent and is well suited for intravenous use in situations where high blood levels of Methylprednisolone are required rapidly. Sterile Powder form of Injection is technologically advanced form of Injection and are manufacturing cost involved in such form of Injection is very high as compared to the Suspension for Injection.
 - (h) NPPA while calculating the Ceiling Price should have considered the pack wise price of 1ml, 2ml and 5ml packs of Methylprednisolone Acetate Suspension for Injection.
 - (i) Similarly, pack-wise price for Methylprednisolone Sodium Succinate Injection in Sterile Powder form should have been considered for calculating Ceiling Price.
- Submission:
 - (1) NPPA may please be directed to rework the pack wise Ceiling Price for Methylprednisolone Acetate Suspension for Injection.
 - (2) NPPA may also be directed to rework the Ceiling Price for Methylprednisolone Sodium Succinate Sterile Powder for Injection.

NPPA's reply:

NPPA representative submitted that the ceiling price of Methylprednisolone 40mg/ml injection as per data available in Pharmatrac for the month of August, 2015. NLEM 2015 has not made any differentiation between injection and powder for injection.

5. Examination:

NPPA has fixed the ceiling price of Methylprednisole 40mg/ml injection by considering the PTR of 1ml, 2ml and 5ml pack sizes. NPPA also considered the per ml PTR of company's product Depotex 40 injection and various other formulations, which

are in powder form having different composition for fixing the ceiling price of subject formulation.

5.2 The petitioner company, in support of their claim, has submitted that the therapeutic advantage of Methylprednisolone Sodium Succinate Powder for injection is that it is soluble in water and may be administered in a small volume of diluents and is well suited for intravenous use in situations where high blood levels of Methylprednisolone are required rapidly. The company further stated that sterile powder form of injection is technologically advanced form of injection and manufacturing cost involved in such form of injection is very high as compared to Suspension for Injection. The company also submitted various supporting documents.

5.3 Keeping in view the therapeutic advantages elaborated by the company, it is proposed that NPPA may be directed to refer the matter to Expert Committee for their opinion. There is a provision in DPCO as per Para 11(3&4) that a Committee of Expert may recommend fixing of separate ceiling price of scheduled formulations or retail price for such formulations with specific therapeutic rationale, considering the type of packaging or pack size, or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be.

5.4 Committee of Experts should examine and recommend whether separate ceiling price based on its pack sizes be fixed and also the therapeutic rationale of the formulation Methylprednisolone Sodium Succinate Powder for injection, to decide about separate pricing of Methylprednisolone Injection as Suspension for Injection and Methylprednisolone Sodium Succinate Powder for Injection. The recommendation of the Expert Committee may be examined by NPPA and take a decision about refixation/revision of ceiling price of Methylprednisole 40mg/ml injection, on merit.

6. **Government Decision:**

“NPPA is hereby directed to refer the matter to Committee of Experts to examine and recommend whether separate ceiling price based on its pack sizes be fixed and also the therapeutic rationale of the formulation Methylprednisolone Sodium Succinate Powder for injection, to decide about separate pricing of Methylprednisolone Injection as Suspension for Injection and Methylprednisolone Sodium Succinate Powder for Injection. The recommendation of the Expert Committee may be examined by NPPA to take a decision about refixation/revision of ceiling price of Methylprednisole 40mg/ml injection, on merit.”

Issued on this date of 30th day of October, 2017.

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

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**

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**