

**No. 31015/26/2017-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 Pfizer Products India Private Limited against price fixation of “Solu Medrol 40mg/ml (containing Methylprednisolone-40mg/ml)” 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 21.02.2017
- 2) NPPA notification under review S.O. 248(E), dated 24.01.2017
- 3) Record Note of discussions held in the personal hearing held in the matter on 05.09.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Pfizer Products India Private 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 Solu Medrol 40mg/ml (containing Methylprednisolone-40mg/ml).

2. The petitioner has contended as under:-

(i) NPPA had uploaded on its website the draft version of proposed price calculation Sheet in respect of ‘Methylprednisolone injection Methylprednisolone-40 mg/ml vide Office Memorandum No. 8(34)/2016/DP/NPPA/Div.II dated 26.10.2016. Company submitted that there were several anomalies and errors in the above draft price calculation sheet issued on October 26, 2016.

(ii) Company had made a detailed representation in this respect to NPPA pointing out inter alia that the Price to Retailer for company’s formulation Solu Medrol 40 mg/ ml injection has been incorrectly considered by the NPPA in their draft price calculation sheet and also brought to the attention of NPPA various other anomalies and errors in the draft price calculation sheet. In order to validate company’s claim, NPPA had sought for copies of invoices of August 2015, which was duly provided by company. However NPPA has notified the ceiling price of Methylprednisolone Injection 40 mg/ml without any consideration to the discrepancies pointed out by company.

(iii) **Grounds:**

a. In the draft price working sheet, NPPA has considered a price per unit of Rs.10.06 for a non-existent pack size of 5 ml of Depo Medrol 40 mg Injection. This is totally wrong as Company does not manufacture or market Depo Medrol 40 mg 5 ml pack size. In spite of this, the draft price working sheet indicated a market share of

83.94% against this SKU. If the price of this non-existent formulation is taken out of the draft price working sheet, the ceiling price would have changed to Rs. 50.07 as against the notified price of Rs. 44.53.

b. The Price to Retailer for company's formulation Solu Medrol 40 mg/ ml was incorrectly considered in the draft price calculation sheet as Rs. 53.92 whereas the Price to Retailer for this formulation was Rs. 57.33. If the correct price of company's formulation was taken into consideration and the non-existent pack size of Depo Medrol 5 ml is excluded, the average ceiling price would have changed to Rs. 50.71.

c. The price per unit of a major competitor's brand having a Price to Retailer of Rs.108.95 has been considered as Rs. 59.53 in the draft price working sheet. The product label of the competitor's product indicates Methylprednisolone Sodium succinate equivalent to Methylprednisolone 40 mg and 4 ml diluent. As per the package insert, for reconstitution of the 40 mg formulation, 1 ml of bacteriostatic water for injection (diluent) is to be used. The remaining 3 ml of diluent in this 40 mg SKU is consequently redundant for reconstitution of this formulation. Consequently, the PTR at Rs. 108.95 of this product should be the actual comparable price for all other Methylprednisolone Injections 40 mg per ml products to be considered in the draft price calculation sheet. If this anomaly is rectified and the correct PTR of the competitor was considered along with the errors pointed out in (a) and (b) above, the ceiling price for the formulation Methylprednisolone Injection 40 mg / ml would have change to Rs.60.00 per ml.

(iv) In view of the above, Company requested to set aside the Price Notification No. S.O. 248(E) dated January 24, 2017 and direct NPPA to rectify the errors and refix the ceiling price Methylprednisolone Injection 40 mg / ml in accordance with the provisions of DPCO by considering the correct PTR.

### 3. Comments of NPPA:

I. Ceiling price of **Solu Medrol 40 mg/ml injection (containing Methylprednisolone-40mg/ml)** was notified as Rs. 44.53/ml vide S.O. 248(E) dated 24.01.2017 and revised to Rs. 45.41 vide S.O. 2059(E) dated 30.06.2017 as per para 4, 6, 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 **Solu Medrol 40 mg/ml injection (containing Methylprednisolone-40mg/ml)**. 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.	Company has stated that they have submitted representation vide letter dated 28.11.2016 against the anomalies and errors in draft price calculation sheet. Company also pointed out that they have provided copies of invoices of August 2015. NPPA has not considered their	The company has not submitted all the requisite documents as per OM 8(34)/2014/Div/ II/DP/NPPA dated 10.10.2016 within 10 working days from the date of uploading of the draft working sheet on NPPA's website dated 26.10.2016.

<p>representation. Ceiling Price fixed by NPPA for Methylprednisolone-40mg/ml is not in consonance with the provisions of DPCO, 2013 on the following grounds:-</p> <p>(i) NPPA has considered a price per unit of Rs. 10.06 for a non-existent pack size of 5 ml of Depo Medrol 40mg Injection. This is totally wrong as our Company does not manufacture or market Depo Medrol 40 mg 5 ml pack size. In support of their claim, company has submitted copy of Form-V.</p> <p>(ii) Company pointed out that price to Retailer for their formulation Solu Medrol 40 mg/ml was incorrectly considered in the draft price calculation sheet as Rs. 53.92 whereas the Price to Retailer for this formulation was Rs. 57.33.</p> <p>(iii) The price per unit of a major competitor's brand having a Price to Retailer of Rs. 108.95 has been considered as Rs. 59.53 in the draft price working sheet. The product label of the competitor's product indicates Methylprednisolone Sodium succinate equivalent to Methylprednisolone 40 mg and 4 ml diluent. As per the package insert, for reconstitution of the 40 mg formulation, 1 ml of bacteriostatic water for injection (diluent) is to be used. The remaining 3 ml of diluent in this 40 mg SKU is consequently redundant for reconstitution of this formulation. Consequently, the PTR at Rs. 108.95 of this product should be the actual comparable price for all other Methylprednisolone injections 40 mg per ml products to be considered in the draft price calculation sheet.</p>	<p>NPPA has fixed the ceiling price for Methylprednisolone-40mg/ml Injection as per data provided by AIOCD-AWACS for the month of August 2015. The company has not submitted all the requisite documents as per OM 8(34)/2014/Div/ II/DP/NPPA dated 10.10.2016 within 10 working days from the date of uploading of the draft working sheet on NPPA's website dated 26.10.2016.</p> <p>In this regard, it is stated that the price has been taken based on the derived PTR by restricting up to the existing ceiling price notified in earlier existing notification. Hence, representation of company has no merit.</p>
--	--

III. Company has not challenged in any Court in respect of ceiling price fixation for Solu Medrol 40 mg/ml injection (containing Methylprednisolone-40mg/ml) vide S.O. No. 248(E) dated 24.01.2017.

**4. Examination:**

As regards NPPA considering the price per unit of Rs.10.06 for a non-existent pack of 5ml of Depo Medrol 40mg Injection, the company has submitted necessary documents in support of its claim. It is also observed from the calculation sheet, that the market share of this product is only 0.11%, which is less than 1% of MAT value, and should not be considered while fixing the ceiling price of the formulation. Therefore, NPPA may be directed to re-fix/revise the ceiling price of the subject formulation by not considering the PTR of Depo Medrol 40mg Injection 5ml pack.

5.2 Company also submitted necessary documentary proof in support of its claim about the actual PTR of their formulation Solu Medrol 40mg/ml Injection (containing Methylprednisolone 40mg/ml.) as on August, 2015. Keeping in view the documentary proof submitted by the company, NPPA may be directed to re-fix/revise the ceiling price of Methylprednisolone-40mg/ml, after verification, on merit.

5.3 The grievance of company about not considering the PTR of Rs.108.95 of competitor's company, has got no merit, as NPPA has rightly restricted the price to notified PTR of Rs.59.53/ml of the formulation, as per DPCO, 2013.

**6. Government Decision:**

**“NPPA is hereby directed to re-fix/revise the ceiling price of the Methylprednisolone-40mg/ml, by not considering the PTR of Depo Medrol 40mg Injection 5ml pack, having less than 1% market share of MAT value and also verify the documents submitted by the company about being a discontinued pack.”**

**“NPPA is further directed to consider the information/documents submitted by the company in respect of actual PTR of their formulation Solu Medrol 40mg/ml Injection and re-fix/revise the ceiling price of Methylprednisolone-40mg/ml, after verification, on merit.”**

Issued on this date, the 30<sup>th</sup> day of October, 2017.

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

To

1. M/s. Pfizer Products India Private Limited,  
The Capital, 1802/1901,  
Plot No.C-70, G Block, Bandra Kurla Complex,  
Bandra (East), Mumbai – 400 051.
2. 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