No. 31015/75/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A Wing, Shasttri Bhawan,
New Delhi 110 001

Subject: **Review application of M/s Neon Laboratories Limited against price fixation of their formulation "Methylprednisolone Acetate 40 mg/ml." vide NPPA order No. S.O. 2059(E), dated 30.06.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

Ref: **1) Review application dated 28.07.2017.**
2) NPPA notification under review S.O. No.2059(E), dated 30.06.2017
3) Record Note of discussions held in the personal hearing on 17.10.2017.

1. This is a review petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Neon Laboratories Limited (hereinafter called the petitioner) against notification S.O. No.2059(E), dated 30.06.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Methylprednisolone Acetate 40 mg/ml.

2. The petitioner has contended as under:

I. National Pharmaceutical Pricing Authority (NPPA) issued a notification no S.O. 2059 (E) dated 30th June 2017, fixing prices of 135 Scheduled formulations, inter–alia, including Price of Scheduled formulations Methylprednisolone Acetate 40 mg/ml at Sr. No. 93 after giving effect of Goods and Services Tax (GST) implementation.

II. AND WHEREAS NPPA in its worksheet issued on 24.01.2017**,** had erred by considering both Methylprednisolone Acetate and Methylprednisolone Sodium Succinate.

III. AND WHEREAS, Methyl Prednisolone acetate & Methyl Prednisolone Sodium Succinate are different salts of Methyl prednisolone which are individually used as active ingredients having separate routes of administration and therapeutic uses.

IV. AND WHEREAS, Methylprednisolone Sodium Succinate for Injection with strength as 40mg/vial, 125mg/vial, 500mg/vial & 1000mg/vial which is dry powder injection, wherein route of injection is given as Single Dose (After reconstitution with diluents) by IV/IV Infusion & Intra Muscular. However, Methylprednisolone Acetate Injection 40mg/ml is liquid injectable suspension & route of injection is by Intra-Muscular, Intra-articular & intralesional. Secondly, method of manufacturing for both the products is solely different & excipients used in both the formulations are different. Thus, both the dosages Methylprednisolone Sodium Succinate & Methylprednisolone Acetate are different.

V. AND WHEREAS, Methylprednisolone Acetate must be consider as Non Scheduled formulation under DPCO 2013.

Under the circumstances:

a. Both the aforesaid formulations; Methylprednisolone Sodium Succinate and Methylprednisolone Acetate were incorrectly deemded by NPPA as Scheduled formulations;

b. The root of administration & theropetic value of Methylprednisolone Acetate 40mg/ml is widely different from Methylprednisolone Sodium Succinate;

c. NPPA has erred by issuing ceiling price for Non Scheduled Methylprednisolone Acetate 40mg/ml ;

VI. In view of above, company requested as under:

(i) To consider and conclude that Methylprednisolone Acetate 40mg/ml is Non Scheduled formulation and NEON may be allow to rever to Maximum Retail Price as applicable prior to notification to ceiling price by NPPA.

(ii) To consider and conclude that the ceiling price of Methylprednisolone Sodium Succinate 40mg/ml must be renotify.

(iii) Pass a speaking order in respect hereof.

(iv) Any other order in interest of this manufacturer.

3. **Comments of NPPA:**

3.1 Ceiling price of **Methylprednisolone Injection 40 mg/ml** was notified as Rs. 45.41/ml vide S.O. 2059(E) dated 30.06.2017 **and the same was again revised to Rs. 43.55/ml vide SO 2400(E) dated 28.07.2017** as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

3.2 The company has stated that correct methodology was not followed in arriving at the ceiling price of **Methylprednisolone Injection 40 mg/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 to 6	Company has stated that NPPA issued S.O. 2059(E) dated 30.06.2017 which includes price of scheduled formulation **Methylprednisolone Acetate 40 mg/ml** also, after giving the effect of Goods and Services Tax (GST) implementation.	The company has made representation against S.O. 2059(E) dated 30.06.2017 which was issued only to give the effect of GST. As far as the issue raised by the company for inclusion of **Methylprednisolone Acetate and Methylprednisolone Sodium Succinate** in the worksheet

	As per company opinion, NPPA had erred by considering both **Methylprednisolone Acetate and Methylprednisolone Sodium Succinate** in its worksheet issued on 24.01.2017. **Methylprednisolone Acetate and Methylprednisolone Sodium Succinate** are differed salts of **Methylprednisolone** which are individually used as active ingredients having separate roots of administration and theraupatic uses. In addition, **Methylprednisolone Sodium Succinate injection** are available in the market with strength as 40 mg/vial, 125 mg/vial, 500mg/vial and 1000mg/vial which is dry powder injection where in root of injection is given as single dose (after reconstitution with diluents). However, **Methylprednisolone Acetate Injection 40mg/ml** is liquid injectable suspension. Method of manufacturing for both the products is solely different and excipients used in both the formulation are different. Company requested to consider **Methylprednisolone Acetate** as non-scheduled formulation and M/s Neon Ltd. may be allowed to rever to Maximum Retail Price as applicable prior to notification to ceiling price by NPPA.	uploaded by NPPA for notifying the price of **Methylprednisolone Acetate 40mg/ml** vide notification S.O. 248(E) dated 24.01.2017 is concerned, it has become time barred. Further, it may also be informed that Methylprednisolone Injection 40mg/ml is included under NLEM 2011 as well as NLEM 2015 of DPCO, 2013. DPCO does not differentiate about the API (Methylprednisolone Acetate / Methylprednisolone Sodium Succinate) used during the manufacturing process of Methylprednisolone injection. Consideration of **Methylprednisolone Acetate and Methylprednisolone Sodium Succinate** in the worksheet issued on 24.01.2017 is within the provision of DPCO, 2013. Therefore, issue raised by company has no merit. Request of company to consider **Methylprednisolone Acetate** as non-scheduled formulation is also not tenable.

3.3 Company has not challenged S.O. No. 2059(E) dated 30.06.2017 in any Court.

4. Examination:

NPPA has notified SO 2059(E), dated 30.06.2017 only to revise ceiling prices to be applicable consequent to the implementation of Goods and Services Tax (GST).

4.2 NPPA has fixed the ceiling price of Methylprednisolone Injection 40 mg/ml vide SO 248(E), dated 24.01.2017. The company, in its review petition, also referred the worksheet issued on 24.01.2017. Hence, technically the grievance raised is now time barred.

4.3 The issue raised by the company in its review application has got no merit as DPCO does not differentiate about the API (Methylprednisolone Acetate / Methylprednisolone Sodium Succinate) used during the manufacturing process of

Methylprednisolone injection. Consideration of **Methylprednisolone Acetate and Methylprednisolone Sodium Succinate** in the worksheet issued on 24.01.2017 is within the provision of DPCO, 2013.

4.4 In view of the above, since the **NPPA has notified SO 2059(E), dt.30.6.2017 only to notify the prices to be followed consequent to the implementation of Goods and Services Tax (GST) with effective from 1.7.2017 and not meant to re-fix the ceiling price of any formulation. Hence, the grievances raised by the petitioner company have got no relevance.**"

5. **Government Decision:**

"NPPA notified SO 2059(E), dated 30.6.2017 only to notify the prices to be followed consequent to the implementation of Goods and Services Tax (GST) with effect from 1.7.2017 and not to re-fix the ceiling price of any formulation. Hence, the grievances raised by the petitioner company have got no relevance and the petition is rejected."

Issued on this date, the 10th day of January, 2018.

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

To

1. **M/s. Neon Laboratories Limited,**
   140, Damji Shamji Ind. Complex,
   M. Caves Road, Andheri (E),
   Mumbai-400 093.
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**