

**No. 31015/78/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

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**A- Wing, Shastri Bhawan,
New Delhi 110 001**

Subject: Review application of M/s Palsons Derma Private Limited against price fixation of “Betamethasone Lotion 0.05%” vide NPPA order No. S.O. 2397(E), dated 28.07.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 03.08.2017
2) NPPA notification under review S.O. 2397(E), dated 28.07.2017
3) Record Note of discussions held in the personal hearing held in the matter on 21.11.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Palsons Derma Private Limited (hereinafter called the petitioner) against notification S.O. No.2397(E), dated 28.07.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Betamethasone Lotion 0.05%.

2. The petitioner has contended as under:-

I. National Pharmaceutical Pricing Authority (NPPA) issued a notification no S.O. 2397(E) dated 28/07/2017, fixing prices of Betamethasone Lotion 0.05% under the provisions of para 4 of DPCO, 2013.

II. AND WHEREAS “STERNON 0.05% LOTION 30 ML” containing composition Betamethasone Lotion 0.05% was considered as a Non Scheduled formulation under DPCO, 2013 till 10th March, 2016. NPPA has erred by deriving a Ceiling PTR for company’s Non Scheduled formulation as on August, 2015.

III. AND WHEREAS, NPPA Notification O.M. No. 8(35)/2016/DOP/NPPA/Div.II dated 22nd May, 2017 was released with Draft version of Proposed Price Calculation, and company’s Price Per Unit (PTR/ML) was incorrectly considered at Rs.0.50 instead of Rs.1.93 which is clearly evident from the price calculation sheet as shared by NPPA on 22nd May, 2017.

V. AND WHEREAS, there is no provisions under Para 4 or any other paragraph of DPCO, 2013 which would restrict the ‘Price Per Unit’ of a non-scheduled formulation while calculating the first ceiling price under the method as specified vide Para 4 of DPCO, 2013.

VI. AND WHEREAS the company once again shares the Summary of all invoices for Betamethasone Lotion 0.05% for the month of August, 2015.

Under the circumstances:

- a. NPPA has erred by notifying ceiling price based on an incorrect draft price calculation which was challenged with all the requested documentation.
- b. NPPA must calculate Ceiling price as per provisions of para 4 of DPCO, 2013 after considering invoices as submitted.
- c. NPPA has gone beyond the provisions of DPCO, 2013 by calculating the draft ceiling price of company's formulation with a methodology over and above what is prescribed under Para 4.

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

- (i) To consider and conclude that NPPA had erred in pricing of STERNON 0.05% LOTION 30 ML under Notification no. S.O. 2397(E) dated 28/07/2017.
- (ii) To direct NPPA to calculate ceiling price of STERNON 0.05% LOTION 30 ML under the provisions of Para 4 of DPCO, 2013.
- (iii) Pass a speaking order in respect hereof.
- (iv) Any other order in interest of this manufacturer.

3. Comments of NPPA:

I. Ceiling price of **Betamethasone Lotion 0.05%** was notified as Rs. 0.48/ml vide S.O. 2397(E) dated 28.07.2017 as per para 4, 5, 6, 10, 11, 14, 15, 16, 17, & 18 of DPCO, 2013.

II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Betamethasone Lotion 0.05%**. 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 NPPA has erred by deriving a ceiling PTR for their non-scheduled formulation as on August 2015. In the opinion of the company, their product 'STERNON 0.05% LOTION 30ML' is a non-scheduled formulation. NPPA in their draft version of proposed price calculation considered the PTR of their product Rs. 0.50 against the actual PTR of Rs. 1.93 vide OM no. 8(35)/2016/DOP/NPPA/Div-II dated	NPPA notified ceiling price of Betamethasone Lotion 0.05% as Rs. 0.48/ml vide S.O. 2397(E) dated 28.07.2017 considering the data provided by AIOCD-AWACS for the month of August, 2015. Formulation under reference is a scheduled formulation as decided in 27 th Authority Meeting of NPPA held on 27.03.2016.

	22.05.2017. Company vide their letter no. PDPL/P/1/17 dated 31.05.2017 submitted a letter against OM no. 8(35)/2016/DOP/NPPA/Div-II dated 22.05.2017.	
	Company has also reiterated that there is no provision under para 4 of DPCO, 2013 to restrict the price per unit of a non-scheduled formulation while calculating the ceiling price. Company also submitted the summary of all invoices in support of the claim of their PTR. NPPA did not consider the company's representation. In the review application, company has mentioned that they filed review petition under para 31 of DPCO, 2013 against S.O. 2397(E) dated 28.07.2017.	NPPA fixed the ceiling price Rs. 12.28/30ml for Betamethasone Lotion 0.05% vide SO 1983(E) dated 03.08.2009 under DPCO 1995. As per para 10(2) of DPCO, 2013, company was supposed to follow the ceiling prices. The company did not follow the ceiling price of Betamethasone Lotion 0.05%-30ml. The PTR of their product was restricted as NPPA notified the ceiling price of the subject formulation under DPCO, 1995. Accordingly, NPPA worked out the ceiling price of Betamethasone Lotion 0.05% considering para 10(2) of DPCO, 2013. <u>Issues raised by the company have no merit.</u> As mentioned by the company at serial no. 9 of their review application, company did not submit any supporting documents.

III. As per NPPA's information, Company has not challenged any notification in respect of **Betamethasone Lotion 0.05%** of **M/s Palsons Derma Pvt. Limited** in the Court.

4. During the personal hearing, the representative of the Company stated the formulation was launched by the company in February, 2014, when the formulation was classified as a non-scheduled formulation. In February, 2014, the ceiling price as notified under DPCO, 1995 did not apply to the aforesaid formulation and the MRP was in compliance with para 20 of DPCO, 2013.

4.2 NPPA representative stated that they have no further comments in addition to as stated above.

5. Examination:

NPPA fixed the ceiling price of Betamethasone Lotion 0.05% by considering the PTR of M/s Palsons Derma Pvt. Ltd. and restricted the price to Rs.0.50/per ml. NPPA stated that the ceiling price of Betamethasone Lotion 0.05% was fixed as Rs.12.28/30ml vide SO 1983(E), dated 03.08.2009 under DPCO, 1995 and restricted the PTR of the company's product under para 10(2) of DPCO, 2013.

5.2 Company stated the formulation was launched in February, 2014, when it was classified as a non-scheduled formulation and the MRP was in compliance with para 20 of DPCO, 2013. It may be stated here that para 20 of DPCO, 2013 is meant to monitor the prices of non-scheduled formulations. Since, the formulation Betamethasone Lotion 0.5% has become scheduled formulation in NLEM, 2015, restricting the PTR of Sternon 0.5% Lotion 30ml, being manufactured by M/s Palsons Derma Private Limited, by NPPA, as per para 10(2) of DPCO, 2013, is in order. In view of this, the grievance raised by the company cannot be accepted.

6. **Government Decision:**

“The formulation Betamethasone Lotion 0.5% has become scheduled formulation in NLEM, 2015, and restricting the PTR of Sternon 0.5% Lotion 30ml, being manufactured by M/s Palsons Derma Private Limited, by NPPA, as per para 10(2) of DPCO, 2013, is in order. Therefore, the grievance raised by the company cannot be accepted.”

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. Palsons Derma Private Limited,
10/D/1, Ho-Chi-Minh Sarani,
Kolkata-700 071.
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