

No. 31015/103/2016-PI.I
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 Sun Pharma Laboratories Ltd. against price fixation of “Carboxymethylcellulose Drops 0.5% and Carboxymethylcellulose Drop 1%” vide NPPA order No. S.O. 3432(E), dated 10.11.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref:

- 1) Review application dated 06.12.2016
- 2) NPPA notification under review S.O. 3432(E), dated 10.11.2016
- 3) Record Note of discussions held in the personal hearing held in the matter on 24.01.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharma Laboratories Limited (hereinafter called the petitioner) against notification S.O. No.3432(E), dated 10.11.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Carboxymethylcellulose Drops 0.5% and Carboxymethylcellulose Drop 1%

2. The petitioner has contended as under:-

I. The said notification has revised the ceiling price of Carboxymethylcellulose Drops-0.5%, and Carboxymethylcellulose Drops-1.0% at Sr. No. 1, Sr. No. 2 in NPPA S.O. No. 3432(E). They submitted that they are aggrieved by the said notification as the price calculation has not taken the correct methodology in arriving at the ceiling price, and hence the revision in ceiling price is not justified. they therefore seek a review of the same under paragraph 31 of DPCO 2013 on the following grounds:

(i) In case of Carboxymethylcellulose Drops 1% ceiling price calculation, 1 pack of M/S Mankind Pharmaceuticals Ltd. (LUBISTAR CMC FORTE 1 % EYE DROPS 10 ML) having MAT Market Share less than 1% was considered in the ceiling price calculation.

(ii) In case of Carboxymethylcellulose Drops 0.5% ceiling price calculation, total 5 packs (2 packs of M/S Allergan India Ltd. - RELIEF(ALLERGAN) 0.5% EAR DROPS 5 ML, REFRESH EZEE 0.5 % EYE DROPS 0.4 ML, 1 pack of M/S Cipla Ltd. - FLOGEL 0.50 % EYE DROPS 5 ML, 2 packs of M/S SUNWAYS(INDIA) PVT LTD.- DRU 0.5 % EYE DROPS 10 ML, ULTRA GEL 0.5 % EYE DROPS 10 ML) with MAT Market Share less than 1%, were considered in the ceiling price calculation.

(iii) The methodology adopted in above these 2 instances is in contradiction, and hence does not comply with the provision of DPCO 2013. Para 4(1) of DPCO 2013 explains that –

“The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:.....Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.).....”

II. They enclosed the copy of Form-V of their product packs. In view of the above, they requested this Department to kindly issue necessary directives to NPPA to consider the methodology as per provision of DPCO 2013, and re-fix the ceiling price of captioned formulations.

3. **Comments of NPPA:**

- I. The ceiling price of Rs. 11.85/ml for **Carboxymethylcellulose 0.5% Drops** & Rs. 16.44/ml for **Carboxymethylcellulose 1% Drops** was notified vide S.O. 3432(E) dated 10.11.2016 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 Carboxymethylcellulose 0.5% and Carboxymethylcellulose 1% Drops. 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 Grievances	NPPA comments
1.	Company has stated that PTR and MAT value of Lumbistar CMC forte 1% Eye Drops 10ml of M/s Mankind Pharmaceutical Ltd. has been considered for calculating the ceiling price of Carboxymethylcellulose 1% Drop. Market share of Lumbistar CMC forte 1% Eye Drops 10ml is less than 1% and consideration of PTR and MAT value of Lumbistar CMC forte 1% Eye Drops 10ml for arriving the ceiling price is against the para 4(1) of DPCO, 2013.	M/s Mankind Pharmaceutical Ltd. has another product of same formulation and the combined market share of both the products is more than 1% and hence the PTR of both the products has been taken in the calculation of ceiling price based on the principles of least of three alternatives as decided by Authority in its 27 th meeting held on 29.3.2016. Hence issue raised by company is not tenable. Moreover, the brand name of both the formulations is the same i.e. Lubistar CMC. Manufacturers do so in order to bring down the average and this need to be discouraged.

2.	In case of Carboxymethylcellulose 0.5% Drop total 5 packs (2 packs of M/s Allergan India Ltd.:- Relife (Allergan) 0.5% Ear Drops 5ml, Refresh EZEE 0.5% Eye Drops 0.4ml, 1 pack of M/s Cipla Ltd. :- Flogel 0.5% Eye Drops 5ml, 2 packs of M/s Sunway (India) Pvt. Ltd. :- DRU 0.5% Eye Drops 10ml, Ultra Gel 0.5% Eye Drops 10ml) with market share less than 1%, were considered in the ceiling price calculation.	Issue raised by company with reference to Refresh is not correct. Relife and Refresh Lzee of M/s Allergan India Ltd. are not considered in calculation sheet as their MAT values are less than 1%. The PTR & MAT value of Flogel 0.5% of M/s Cipla Ltd. is also not considered and the PTR & MAT value of DRU 0.5% & Ultra Gel 0.5% of M/s Sunway (India) are also not considered in arriving at the ceiling price for Carboxymethylcellulose 0.5% Drop, their MAT values being less than 1%.
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4. During the personal hearing, the representatives of the company made following further submissions –

1. Ceiling price notified as Rs. 11.59 per ml via NPPA SO 1686(E) dated 27.04.2016.
2. Out of 2 packs of Sun Pharma (Glytears, Tear drops) only one pack viz. Glytears has been considered in the ceiling price calculation. Moreover, 2 packs of M/S Allergan were also not considered in the calculation.
3. Unimed (manufacturer) has filed a representation with relevant documents dated 20.05.2016.
4. NPPA has asked for documents like – MAT, PTR as on August 2015, sample pack copy, invoice copy via letter dated 15.06.2016 (received by company on 30.06.2016).
5. Unimed had provided the required details via letter dated 06.07.2016.
6. NPPA has uploaded the draft working sheet dated 31.08.2016 including 2 pack of Company. (Glytears, Tear drops). However, for Glytears, there was a price difference in PTR displayed (Rs. 135.51 per pack), and actual PTR prevalent in August 2015 (Rs. 146.24 per pack)
7. Unimed filed representation with supporting documents against this PTR difference in the office of NPPA dated 09.09.2016.
8. NPPA notified the ceiling price of Carboxymethylcellulose Drops 0.5% as Rs. 11.85 per ml via SO 3432(E) dated 10.11.2016.
9. In the working sheet of the notification dated 10.11.2016 , total 5 packs (2 of M/s Allergan, 1 of M/s Cipla, 2 of M/s Sunways) with MAT market share less than 1% were considered in the ceiling price calculation.
10. Sun Pharma (marketer) complied with the notified price, and submitted the price list in Form-V dated 02.12.2016.

Carboxymethyl cellulose drops 1% (Teardrops E/D gel 10 ml):

1. Ceiling price notified as Rs. 13.03 per ml via NPPA SO 1686(E) dated 27.04.2016.
2. Sun Pharma's 1 pack Teardrops E/D gel 10 ml was not considered in the ceiling price calculation.

3. Unimed (manufacturer) has filed a representation with relevant documents dated 21.05.2016.
4. NPPA has asked for documents like – MAT, PTR as on August 2015, sample pack copy, invoice copy via letter dated 15.06.2016 (received by company on 30.06.2016).
5. Unimed had provided the required details via letter dated 06.07.2016.
6. NPPA has uploaded the draft working sheet dated 31.08.2016 including 1 pack of company. Teardrops E/D gel 10 ml. However, there was a price difference in PTR displayed (Rs. 127.00 per pack), and actual PTR prevalent in August 2015 (Rs. 137.01 per pack)
7. Unimed filed representation with supporting documents against this PTR difference in the office of NPPA dated 09.09.2016.
8. NPPA notified the ceiling price of Carboxymethylcellulose Drops 1% as Rs. 16.44 per ml via SO 3432(E) dated 10.11.2016.
9. In the working sheet of the notification dated 10.11.2016, 1 pack of M/s Mankind with MAT market share less than 1% were considered in the ceiling price calculation.
10. Sun Pharma (marketer) complied with the notified price, and submitted the price list in Form-V dated 02.12.2016.

The company representatives submitted that the methodology adopted in notifying the ceiling prices of Carboxymethylcellulose Drops 0.5% and Carboxymethylcellulose Drops 1% were contradictory to each other and not as per provision of DPCO 2013 and in support of that submitted copy of review order No.31015/23/2016-PI.I, dated 6th day of October, 2016.

The representatives of the NPPA submitted that the calculation of ceiling price is based on the principles of least of the three alternatives as decided by Authority in its 27th meeting held on 29.3.2016.

5. **Examination:**

The petitioner company has challenged the NPPA S.O. 3432(E), dated 10.11.2016 for price fixation of their formulation **Carboxymethylcellulose Drops 1%**, stating that NPPA has included the PTR and MAT value of Lumbistar CMC forte 1% Eye Drops 10 ml having less than 1% market share. Similarly for price fixation of formulation **Carboxymethylcellulose Drops 0.5%**, total 5 packs (2 packs of M/s Allergan India Ltd. – Relief(Allergan) 0.5% Ear Drops 5ml, Refresh Ezee 0.5 % Eye Drops 0.4 ML, 1 pack of M/s Cipla Ltd. - Flogel 0.50 % Eye Drops 5 ML, 2 packs of M/s Sunways(India) Pvt. Ltd.- DRU 0.5 % Eye Drops 10ml, Ultra Gel 0.5 % Eye Drops 10ml) with MAT Market Share less than 1%, have been considered by NPPA.

On going through the calculation sheet of **Carboxymethylcellulose Drops 1%**, it is observed that NPPA has erred in considering LUBISTAR CMC FORTE 1 % EYE DROPS 10 ML) having MAT Market Share less than 1% (at Sr.No.10 of calculation sheet) while fixing the ceiling price, as DPCO does not recognize a company for average PTR but only medicines / formulations. However, in case of **Carboxymethylcellulose Drops 0.5%**, **NPPA has not included the 5 packs** (2 packs of M/S Allergan India Ltd. - Relief(Allergan) 0.5% Ear Drops 5ml, Refresh Ezee 0.5 % Eye Drops 0.4 ML, 1 pack of M/s Cipla Ltd. - Flogel 0.50 % Eye Drops 5 ML, 2 packs of M/s Sunways(India) Pvt. Ltd.- DRU 0.5 % Eye Drops 10ml, Ultra Gel 0.5 % Eye Drops

10ml) with MAT Market Share less than 1%, **as alleged by the petitioner company.** Hence, for this formulation, the grievance of petitioner company has got no merit.

6. **Government Decision:**

“NPPA is hereby directed to re-fix the ceiling price of Carboxymethylcellulose Drops 1% by excluding LUBISTAR CMC FORTE 1 % EYE DROPS 10 ML) which has MAT Market Share of less than 1%, strictly in accordance with DPCO 2013 para 4(1).”

Issued on this date, the 5th day of April, 2017.

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

To

1. M/s. Sun Pharma Laboratories Limited,
Sun House, Plot No.201 B/1,
Western Express Highway,
Goregaon (E), Mumbai-400 063.
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