

**No. 31015/08/2017-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

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A- Wing, Shastri Bhawan,  
New Delhi 110 001

**Subject:** Three Review applications of M/s Sun Pharma Laboratories Limited against price fixation of "Atracurium Injection 10mg/ml; Sodium Valproate Oral Liquid 200mg/5ml and Trimolol Drops 0.5% Eye Drops" vide NPPA order No. S.O. 4128(E), dated 22.12.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Three Review applications, two applications dated 17.01.2017 and one dated 18.01.2017  
2) NPPA notification under review S.O. 4128(E), dated 22.12.2016  
3) Record Note of discussions held in the personal hearing held in the matter on 30.05.2017.

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.4128(E), dated 22.12.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Atracurium Injection 10mg/ml; Sodium Valproate Oral Liquid 200mg/5ml and Trimolol Drops 0.5% Eye Drops.

2. The petitioner has contended as under:-

**I. In respect of Atracurium Injection 10 mg/ml :-**

(i) Working sheet of Atracurium Injection 10 mg/ml notified under NPPA S.O. No. 4128(E) dated 23.12.2016 captured 4 packs with different volumes in range of 2.5 ml to 5 ml packs. **However, price per unit considered as Rs. 43.09 for each pack, and not as per ml, which does not reflect correct state in the calculation.** It is apparent that price per unit considered as pack in calculation is bad in terms of law, and contrary to price calculation mechanism of DPCO 2013. Ceiling price calculation should be done by taking per ml, as this segment covers with packs of different volumes, and not as per pack.

(ii) It is pertinent to note that this formulation is available in various volumes, and packs, hence per pack price would not hold its appropriateness.

**II. In respect of Sodium Valproate Oral Liquid 200 mg/5 ml:-**

(i) NPPA has presented the draft working sheet of 2 formulations including captioned formulation on NPPA website on 18.10.2016. Displayed draft working

sheet captured 4 packs of the company viz. ENCORATE 200 MG SYRUP 200 ML, ENCORATE 200 MG SYRUP 60 ML, ENCORATE 200 MG SYRUP 100 ML, and EPIVAL 200 MG SYRUP 200 ML. Out of these 4 packs, company had never manufactured/marketed 2 packs viz. ENCORATE 200 MG SYRUP 200 ML, ENCORATE 200 MG SYRUP 60 ML. These 2 packs have been erroneously included in the ceiling price calculation. Further, 1 pack SOVAL 200 MG SYRUP 100 ML of M/S Shine Pharmaceuticals Ltd. having less than 1% SKU market share, has been captured in the price calculation, which is against to para 4(1)of DPCO 2013. Company had submitted their representation dated 27.10.2016 along with necessary documents within 10 working days of draft working sheet presentation on NPPA website.

(ii) NPPA has notified the ceiling price of Sodium Valproate Oral Liquid 200 mg/5 ml via S.O. No. 4128 (E) dated 22.12.2016 without considering their representation. This in turn has led to the fixation of ceiling price based on incorrect methodology, which is beyond the provision of DPCO 2013.

### **III. In respect of Timolol Drops 0.5% Eye Drops:-**

(i) NPPA has presented the draft working sheet of 18 formulations including captioned formulation on NPPA website on 21.10.2016. The sheet captured 4 packs of the company, **out of which 2 packs viz. TIMOLET OD 0.5 % EYE DROPS 3 ML, and TIMOLET GFS 0.5 % DROPS 3 ML are not the conventional formulation, but advanced release formulation.** Since these 2 packs are advanced release formulation, thus should not be considered in ceiling price calculation, as per explanation (2) of Department of Pharmaceuticals' notification S.O. 701 (E) dated 10.03.2016. Company had submitted their representation dated 02.11.2016 along with necessary documents within 10 working days of draft working sheet presentation on NPPA website, and subsequently on 22.11.2016.

(ii) **1 pack which has been considered in the ceiling price calculation - TIMOLET P 0.5 % EYE DROPS 5 ML - is having composition Timolol Maleate and Pilocarpine Nitrate, which is different from Timolol Drops 0.5%. This pack should not be included in ceiling price calculation working sheet.**

IV. In view of the above, company requested this Department to kindly issue necessary directives to NPPA to re-notify the ceiling price of the above said formulations.

### **3. Comments of NPPA:**

- (i) Ceiling price of Rs. 48.63/each pack for **Atracurium 10mg/ml Injection, Rs. 0.54 per ml for Sodium Valproate Oral Liquid 200mg/5ml** and Rs. 11.06 per ml for **Timolol 0.5% Eye Drops** was notified vide S.O. 4128(E) dated 22.12.2016 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.
- (ii) Company has stated that correct methodology was not followed in arriving at the ceiling price for **Atracurium 10mg/ml Injection and Sodium Valproate Oral Liquid 200mg/5ml and Timolol 0.5% Eye 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 39<sup>th</sup> Authority meeting held on 21.12.2016. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	<p>i. <b>Atracurium 10mg/ml Injection</b> - Company has pointed out that NPPA has clubbed the PTR of the packs ranging from 2.5ml to 5ml for calculation the ceiling price which does not reflect correct state in the calculation. NPPA has captured for packs with different volumes in range of 2ml to 5ml.</p>	<p>NPPA has fixed the ceiling price of Rs. 45.28, Rs. 48.14, Rs. 49.99 &amp; 48.64 per pack vide S.O. 1674(E), 1156(E), 619(E) &amp; 644(E) dated 14.6.2013, 28.4.2014, 26.02.2015 &amp; 02.3.2016 respectively under NLEM 2011 of DPCO 2013 and company has not challenged the price fixation order issued by NPPA from time to time. 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. <b>M/s Sun Pharma Industries Limited <u>did not make any representation against the proposed draft ceiling price uploaded on NPPA's website.</u></b></p>
	<p>ii. <b>Sodium Valproate Oral Liquid 200mg/5ml - (a)</b> Company has stated that NPPA has considered Encorate 200mg Syrup 200ml, Encorate 200mg Syrup 60ml, Encorate 200mg Syrup 100ml &amp; Epival 200mg Syrup 200ml for calculating the ceiling price for Sodium Valproate Oral Liquid 200mg/5ml. They had never manufactured/ marketed Encorate 200mg Syrup 200ml &amp; Encorate 200mg Syrup 60ml. (b) Company has also pointed out that NPPA has included the PTR of Soval 200mg Syrup 100ml having the PTR less than 1%.</p>	<p>There is no merit in company's claim NPPA has considered only Encorate 200mg Syrup 100ml &amp; Epival 200mg Syrup 200ml for calculating the ceiling price.</p> <p>NPPA has considered company wise MAT as per the Authority's decision in 27<sup>th</sup> meeting held on 29.3.2016</p>
	<p>iii. <b>Timolol 0.5% Eye Drops -</b> Company has pointed out that PTR of Timolet 0.5% should be considered as 51.76 against the PTR 49.91. company has also challenged the</p>	<p>As per draft working sheet propose ceiling price was Rs. 11.01 per ml and the same was revised &amp; notified to Rs. 11.06/ml considering the PTR of Timolet 0.5% Eye Drop of M/s</p>

	inclusion of Timolet OD 0.5% Eye Drop 3ml and Timolet GFS 0.5% Drops 30ml being innovative dosage.	Sun Pharmaceuticals Laboratories Ltd. Regarding the inclusion of innovative dosage it is stated that as decided in the 27 <sup>th</sup> Authority meeting, all variants of products are taken while determining the ceiling price of a formulation unless different variants of the formulation are specifically mentioned against any formulation in the NLEM 2015. Therefore, company's claim has no merit.
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(iii). Company has not challenged any notification in respect of **Atracurium 10mg/ml Injection and Sodium Valproate Oral Liquid 200mg/5ml and Timolol 0.5% Eye Drops** in the Court.

#### 4. **Examination:**

##### i) **Atracurium Injection 10mg/ml:**

The company has pointed out that NPPA has clubbed the PTR of the packs ranging from 2.5ml to 5ml for calculating the ceiling price which does not reflect the correct state in the calculation. In this connection, it is mentioned that in the absence of mention of any particular pack size in Schedule I of NLEM, 2015, the clubbing of PTR of 2.5ml to 5ml pack sizes is justified. Therefore, the grievance of the company cannot be accepted.

##### ii) **Sodium Valproate Oral Liquid 200mg/5ml**

The Company has stated that NPPA has considered Encorate 200mg Syrup 200ml, Encorate 200mg Syrup 60ml, Encorate 200mg Syrup 100ml & Epival 200mg Syrup 200ml for calculating the ceiling price for Sodium Valproate Oral Liquid 200mg/5ml. They had never manufactured/marketed Encorate 200mg Syrup 200ml & Encorate 200mg Syrup 60ml. Company further pointed out that NPPA has included the PTR of Soval 200mg Syrup 100ml having the PTR less than 1%.

On going through the calculation sheet, it is seen that NPPA has considered only Encorate 200mg Syrup 100ml and Epival 200mg Syrup 200ml for calculation purposes. Hence, there is no merit in the claim of the company. However, NPPA has wrongly considered the PTR of Soval 200mg Syrup 100ml, which is having less than 1% market share, as DPCO does not recognize a company for average PTR but only medicines / formulations. Therefore, NPPA may be directed to re-fix the ceiling price of the formulation Sodium Valproate Oral Liquid 200mg/5ml by considering only those medicines / formulations having MAT value of more than 1% market share.

##### iii) **Timolol 0.5% Eye Drops**

The company, during the personal hearing, submitted that 2 packs viz. Timolet OD 0.5% Eye Drops 3ml and Timolet GFS 0.5% Drops 3 ml are not the conventional

formulation, but advanced release formulation and should not be considered in ceiling price calculation, as per explanation (2) of SO 701(E), dated 10.3.2016. Further, Timolet P 0.5% Eye Drops 5 ml is having composition Timolol Maleate and Pilocarpine Nitrate, which is different from Timolol Drops 0.5% and should not be included in the ceiling price calculation. On going through the calculation sheet, it is seen that although NPPA has included the PTR of Timolet P 0.5% Eye Drops 5 ml, but did not consider the formulation for averaging purpose as the market share of the formulation is less than 1%.

In reply to company's claim that their two packs viz. Timolet OD 0.5% Eye Drops 3ml and Timolet GFS 0.5% Drops 3 ml are advanced release formulation, NPPA stated that they have included these formulations based on 27<sup>th</sup> Authority meeting decision. The company is claiming that these two formulations (Timolet OD 0.5% Eye Drops 3ml and Timolet GFS 0.5% Drops 3 ml) are not conventional formulations, but are advance release formulations. As per Explanation (2) of DoP's SO 701(E), dated 10.3.2016, formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/controlled release etc. should be considered as included only if specified in the list against any medicine. In view of this, NPPA may be directed to have the opinion of Expert Committee about the inclusion/exclusion of the formulations Timolet OD 0.5% Eye Drops 3 ml and Timolet GFS 0.5% Drops 3 ml based on their therapeutic rationale and revise the ceiling price of Timolol 0.5% Eye Drops, on merit.

5. **Government Decision:**

**“In the absence of mention of any particular pack size in Schedule I of NLEM, 2015 for Atracurium Injection 10mg/ml, the request of the company against clubbing the PTR of the packs ranging from 2.5ml to 5ml for calculating the ceiling price of the subject formulation cannot be accepted.”**

**“NPPA is further directed to refix the ceiling price of the formulation Sodium Valproate Oral Liquid 200mg/5ml by considering only those medicines / formulations having MAT value of more than 1% market share.”**

**“NPPA is also directed to have the opinion of Expert Committee about the inclusion/exclusion of the formulations Timolet OD 0.5% Eye Drops 3 ml and Timolet GFS 0.5% Drops 3 ml based on their therapeutic rationale and revise the ceiling price of Timolol 0.5% Eye Drops, 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. Sun Pharm Laboratories Limited,  
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Mumbai-400063.
2. Member Secretary,  
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YMCA Cultural Centre Building,  
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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