

No. 31015/68/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Two review applications of M/s Abbott Healthcare Pvt. Limited against price fixation of their formulations "Sodium Valproate - CR Tablets 300mg and Sodium Valproate - CR Tablets 500mg" vide NPPA order No. S.O. 1687(E), dated 24.05.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Two review applications, both dated 16.06.2017
2) NPPA notification under review S.O. No.1687(E), dated 24.05.2017
3) Record Note of discussions held in the personal hearing on 10.10.2017.

1. These are two petitions under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Abbott Healthcare Pvt. Limited (hereinafter called the petitioner) against notification S.O. No.1687(E), dated 24.05.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Sodium Valproate - CR Tablets 300mg and Sodium Valproate - CR Tablets 500mg.

2. The petitioner has contended as under:

(i) Company submitted that NPPA has not considered MAT value & PTR data of M/s Sun Pharma who is a major player in this molecule.

(ii) M/s Sun Pharma's data as per AWACS dataset as given below:-

SKU Name	Company	Aug'15	
		PTR	MAT VAL (RS.)
Encorate Chrono 300 mg tablet 10	Sun Pharma Laboratories Limited	52.34	21,98,63,785
Encorate Chrono 300 mg tablet 10	Sun Pharma Laboratories Limited	83.90	29,69,90,018

(iii) In view of above, company requested to advise NPPA to correct the apparent variance in calculation.

3. Comments of NPPA:

I. Ceiling price of **Sodium Valproate – CR tablet 300mg and 500mg** was notified as Rs. 5.73/tablet and 8.82/tablet vide S.O. 1687(E) dated 24.05.2017 and revised to Rs. 5.50/tablet and Rs. 8.46/tablet vide S.O. 2058(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 **Sodium Valproate – CR tablet 300mg and 500mg**. 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
	<p>Company pointed out as follows:</p> <p>Sodium Valproate CR-500 mg Tab: NPPA has not considered the PTR of Rs.83.90 and MAT value of Rs. 296990018 of Encorate Chrono 500 mg Tab 10 of M/s. Sun Pharma Laboratories Limited while calculating the ceiling price for Sodium Valproate CR-500 mg Tab</p> <p>Sodium Valproate CR-300 mg Tab: NPPA has not considered PTR of Rs. 52.34 and MAT value of Rs.219863785 of Encorate Chrono 300 mg Tab 10 of M/s. Sun Pharma Laboratories Limited for working out the ceiling price for Sodium Valproate CR-300 mg Tab.</p>	<p>NPPA considered the data provided by AIOCD-AWACS for month of August 2015 for fixing the ceiling price of Sodium Valproate – CR tablet 300mg and 500mg. 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. M/s Abbott Healthcare Pvt. Limited did not make any representation against the proposed retail price uploaded on NPPA's website.</p>

- III. Company has not challenged any notification in respect of **Sodium Valproate – CR tablet 300mg and 500mg** of **M/s Abbott Healthcare Pvt. Ltd. Limited** in the Court.

4. During the personal hearing, the representatives of the company submitted documentary proof in support of its claim of Sun Pharma's brand Encorate Chrono 300 and Encorate Chrono 500 having MAT value of Rs.21.98 lakhs and Rs.29.69 lakhs respectively.

NPPA representative did not make any further submission in addition to the written submissions.

5. Examination:

In the instant case, the company claimed that the MAT values of Encorate Chrono 300mg and Encorate Chrono 500mg, being manufactured by M/s Sun Pharma Laboratories Ltd., are Rs.21.98 crores and Rs.29.69 crores respectively. The PTR of 10's pack of Encorate Chrono 300mg and 500mg is Rs.52.34 and Rs.83.90 respectively. It is seen from the documentary proof submitted by the petitioner that the formulations being manufactured by M/s Sun Pharma Laboratories Ltd. contain Sodium Valproate CR tablets, and should be considered while arriving at the average ceiling prices of the formulations under consideration. It is also observed from the calculation sheet that the MAT value of Sodium Valproate CR tablet 300mg is Rs.52.76 crores,

whereas the drug being manufactured by Sun Pharma has MAT value of Rs.21.98 crores, which is well above 1% of total market share. Similarly, the MAT value of Sodium Valproate CR tablet 500mg is Rs.57.09 crores and the drug being manufactured by Sun Pharma has MAT value of Rs.29.69 crores, which is also well above 1% market share. The company has submitted documentary proof in support of its claim. On going through the documentary proof submitted by the company, it is observed that the claim of the company has got merit.

5.2 In view of the above, NPPA may be directed to consider refixing/revising the ceiling prices of Sodium Valproate CR tablets 300mg and 500mg., after verification of information/documentary proof submitted by the petitioner company, on merit.

6. **Government decision:**

“NPPA is hereby directed to examine information/documentary proof submitted by the petitioner company, in respect of MAT value of Encorate Chrono 300mg and Encorate Chrono 500mg being manufactured by M/s Sun Pharma Laboratories Ltd., and after verification, refix/revise the ceiling price of Sodium Valproate CR tablets 300mg and 500mg., on merit.”

Issued on this date of 28th day of November, 2017.

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

To

- 1. M/s. Abbott Healthcare Pvt. Limited,
D Mart Building,
Goregaon Mulund Link Road,
Mulund West, Mumbai-400 080.**
- 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**