

No. 31015/101/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

.....

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

Subject: Review application of M/s Sun Pharma Laboratories Ltd. against price fixation of "Lithium 300 mg" vide NPPA order No. S.O. 3181(E), dated 07.10.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 28.10.2016
2) NPPA notification under review S.O. 3181(E), dated 07.10.2016
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 Ltd.(hereinafter called the petitioner) against notification S.O. No.3181(E), dated 07.10.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Lithium 300 mg

2. The petitioner has contended as under:-

I. The said notification has revised the ceiling price of Lithium 300 mg Tablet at Sr. No. 1 in NPPA S.O. No. 3181(E). They submitted that they are aggrieved by the said notification as the ceiling price calculation has not taken the correct price data and as per provision of DPCO 2013, 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) NPPA has presented the draft working sheet of 35 formulations including captioned formulation on NPPA website on 13.07.2016. Displayed Draft working sheet captured the Price To Retailer (PTR) of LITHOSUN 300 MG TABLET 10 different form the actual PTR applicable in August 2015. They had submitted our representation dated 25.07.2016 along with necessary documents within 10 working days of draft working sheet presentation on NPPA website.

(ii) **NPPA has notified the ceiling price of Lithium 300 mg Tablet via S.O. No. 3181(E) dated 07.10.2016 without considering their representation.** This in turn has led to the fixation of ceiling price based on incorrect PTR data, which is not correct as per the provision of DPCO 2013. Considering such scenario, it seems that overall purpose of bringing transparency in ceiling price calculation/fixation is being defeated.

II. They also enclosed a copy of Price List in Form V of DPCO 2013, confirming implementation of the captioned Ceiling Price of LITHOSUN 300 MG TABLET

10vide NPPA S.O. No. 3181(E) dated 07.10.2016 under revised schedule-I (NLEM 2015) of DPCO 2013.

III. In view of the above, they requested this Department to kindly issue necessary directives to NPPA to consider their representation and to recalculate the ceiling price of the above said formulation.

3. **Comments of NPPA:**

- (i) In this regard, it is mentioned that ceiling price of Rs. 1.35/tablet for **Lithium 300mg tablet** was notified vide S.O. 3181(E) dated 07.10.2016 as per para 4, 10, 11, 14, 16, 17 & 18 under DPCO 2013.
- (ii) NPPA has considered the actual PTR of Lithosun 300mg tablet as provided by pharmaTrac database by (AIOCD-AWAC) for the month of August, 2015.
- (iii) NPPA examined the representation submitted by M/s Sun Pharma Laboratories Ltd. the same was sent to pharmaTrac for confirmation. PharmaTrac confirmed that earlier data as submitted by Pharma Trac was correct. Ceiling price Rs. 1.35/tablet notified for Lithium 300mg tablet is based on correct PTR. Therefore **representation made by M/s Sun Pharma** was not considered by NPPA.

4. During the personal hearing, the representatives of the company made following further submissions -

1. Draft working sheet uploaded on NPPA website on 13.07.2016.
2. There was a difference in PTR displayed in draft working sheet (Rs.12.12 per 10's pack) and actual PTR prevalent in August 2015 (Rs.12.58 per 10's pack).
3. Sun Pharma filed representation with supporting documents against this PTR difference in the office of NPPA on 25.7.2016.
4. NPPA notified the ceiling price of Lithium 300 mg tablets as Rs.1.35 per tablet without considering PTR of Sun Pharma's product Lithosun as Rs.12.58 per 10's pack vide SO 3181(E), dated 7.10.2016.
5. Company submitted Invoice copy of 6th August, 2015 showing PTR of 12.58 per 10's pack.

NPPA representative submitted that the representation submitted by M/s Sun Pharma Laboratories Ltd. based on draft working sheet prior to notification, was examined and the same was sent to PharmaTrac for confirmation. PharmaTrac confirmed that the PTR provided by them was correct. Accordingly, the ceiling price of Lithium 300mg tablet was notified. Therefore, representation made by M/s Sun Pharma was not considered by NPPA.

5. **Examination:**

The petitioner company has challenged the NPPA Order S.O. 3181(E), dated 07.10.2016 for price fixation of their formulation **Lithium 300 mg**, on the ground that NPPA has not included actual PTR of Lithosun 300 mg tablet which is applicable in August, 2015. The representation submitted by the company in this regard against the draft working sheet was not considered by NPPA.

NPPA clarified that the actual PTR of Lithosun 300mg tablet was considered as provided in Pharmatrac database for the month of August, 2015. The representation submitted by M/s Sun Pharma Laboratories Limited was examined by NPPA and sought confirmation from Pharmatrac. Pharmatrac confirmed that earlier data as submitted was correct and the ceiling price Rs.1.35/tablet notified for Lithium 300mg tablet is based on correct PTR. Therefore, the representation made by M/s Sun Pharma Laboratories Limited was not considered by NPPA.

In view the above, since the representation of the petitioner company was duly examined by NPPA and Pharmatrac also confirmed the data submitted earlier, there remains no point in considering the representation of the petitioner company. Therefore, the representation of the petitioner company may be rejected.

6. Government Decision:

“The grievance raised by M/s Sun Pharma Laboratories Ltd. in their review petition has got no merit and hence the petition stands rejected.”

Issued on this date, the 14th day of June, 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