

**No. 31015/89/2017-Pricing
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 Limited against price fixation of their formulations "Sumatriptan Tablet 25mg and Sumatriptan Tablet 50mg" vide NPPA order No. S.O. 3088(E), dated 20.09.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application, dated 18.10.2017
2) NPPA notification under review S.O. No.3088(E), dated 20.09.2017
3) Record Note of discussions held in the personal hearing on 14.11.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharma Laboratories Limited (hereinafter called the petitioner) against notification S.O. No.3088(E), dated 20.09.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Sumatriptan Tablet 25mg and Sumatriptan Tablet 50mg.

2. The petitioner has contended as under:

I. Suminat 25

(i) The draft working sheet of Sumatriptan Tablet 25 mg was displayed on the NPPA website on 25.08.2017.

(ii) In the draft working sheet of Sumatriptan Tablet 25 mg, PTR of company's product pack Suminat 25 mg Tablet 1 was erroneously captured as Rs. 32.33 in the ceiling price calculation instead of PTR Rs. 35.41 applicable in the month of August 2015.

II. Suminat 50

(iii) The draft working sheet of Sumatriptan Tablet 50 mg was displayed on the NPPA website on 25.08.2017.

(iv) In the draft working sheet of Sumatriptan Tablet 50 mg, PTR of company's product pack Suminat 50 mg Tablet 1 was erroneously captured as Rs. 50.05 in the ceiling price calculation instead of PTR Rs. 53.88 applicable in the month of August 2015.

III. In view of above, company requested this Department to issue necessary directive to NPPA to re-notify the ceiling price of Sumatriptan Tablet 25 mg, Sumatriptan Tablet 50 mg.

3. **Comments of NPPA:**

1. Ceiling price of **Sumatriptan Tab 25mg and 50mg** was notified as Rs. 30.21/tablet and 46.76/tablet vide S.O. 3088(E) dated 20.09.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

2. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Sumatriptan Tab 25mg and 50mg**. 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.	<u>Sumatriptan Tab 25mg</u> Based on working sheet, company has stated that NPPA has considered PTR of their product Suminat 25 as Rs. 32.33/tablet against the actual PTR in August, 2015 of Rs. 35.41/tablet.	PTR issue raised by company has no merit. The company furnished the documents relating to PTR after uploading of the draft working sheet in NPPA's website. The documents submitted by the company was sent to AIOCD-AWACS/Pharmatrac for verification. Pharmatrac in its reply stated that the PTR stated by the company was having the less count, therefore, the PTR stated by the company was not considered in calculation by the Authority.
2.	<u>Sumatriptan Tab 50mg</u> Based on working sheet, company has stated that NPPA has considered PTR of their product Suminat 50 as Rs. 50.05/tablet against the actual PTR in August, 2015 of Rs. 53.88/tablet.	PTR issue raised by company has no merit. The company furnished the documents relating to PTR after uploading of the draft working sheet in NPPA's website. The documents submitted by the company was sent to AIOCD-AWACS/Pharmatrac for verification. Pharmatrac in its reply stated that the PTR stated by the company was having the less count, therefore, the PTR stated by the company was not considered in calculation by the Authority.
	Company has claimed that they had submitted representation dated 04.09.2017 against the draft working sheet of above mentioned 2 formulations within 10 working days but correct PTR of their products were not considered in ceiling price calculation.	PTR issue raised by company has no merit. The company furnished the documents relating to PTR after uploading of the draft working sheet in NPPA's website. The documents submitted by the company was sent to AIOCD-AWACS/Pharmatrac for verification. Pharmatrac in its reply stated that the PTR stated by the company was having the less count, therefore, the PTR stated by the company was not considered in calculation by the Authority.

3. Company has not challenged any notification in respect of **Sumatriptan Tab 25mg and 50mg** of **M/s Sun Pharma Laboratories Limited** in the Court.

4. During personal hearing company representative has submitted following:

Sumatriptan Tab 25mg

Company representative submitted that product packs Suminat 25mg were available with revised price (MRP Rs.46.00 and PTR Rs.35.41) for a pack of 10 tablets in August, 2015.

Pharmatrac has also accepted that the availability of stock with PTR Rs.35.41 in the month of August, 2015. Just because of having less count, company should not be made deprived of their claim by not considering PTR Rs.35.41 in ceiling price calculation, which is also not as per DPCO provisions.

Sumatriptan Tab 50mg

Company representative submitted that product packs Suminat 50mg were available with revised price (MRP Rs.70.00 and PTR Rs.53.88) for a pack of 10 tablets in August, 2015.

Pharmatrac has also accepted that the availability of stock with PTR Rs.53.88 in the month of August, 2015. Just because of having less count, company should not be made deprived of their claim by not considering PTR Rs.53.88 in ceiling price calculation, which is also not as per DPCO provisions.

The relevant documents for both the products were submitted along with representation

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

5. Examination:

In the instant case, the company's contention is that NPPA has taken into account wrong and incorrect PTR of their product Suminat 25 mg Tablet 1 as Rs.32.33 in the ceiling price calculation instead of PTR Rs. 35.41 applicable in the month of August 2015. Similarly, for Sumatriptan Tablet 50 mg, actual PTR of company's product pack Suminat 50 mg Tablet 1 is Rs.53.88 whereas NPPA captured as Rs.50.05. In support of its claim, the company submitted necessary supporting documents. Since the company has submitted all necessary documents in support of its claim of actual PTR of the company's products for the month of August, 2015, the stand of Pharmatrac for not considering actual PTR of the company, having less count, is not justified. In view of the above, NPPA may be directed to examine the documentary proof submitted by the company about the actual PTRs of their formulations Suminat 25 mg Tablet 1 and Suminat 50 mg Tablet 1 and, after verification, re-fix/revise the ceiling prices of Sumatriptan Tablet 25mg and Sumatriptan Tablet 50mg, on merit.

6. **Government Decision:**

“NPPA is hereby directed to examine the documentary proof submitted by the company about the actual PTRs of their formulations Suminat 25 mg Tablet 1 and Suminat 50 mg Tablet 1, and after verification, re-fix/revise the ceiling prices of Sumatriptan Tablet 25mg and Sumatriptan Tablet 50mg, on merit.”

Issued on this date of 10th day of January, 2018.

(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-400063.**
- 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**