

No. 31015/85/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhawan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO, 2013

Subject: Review application of M/s. Sun Pharma Laboratories Ltd. against fixation of ceiling price of “Imatinib Mesylate 100 mg tablet” vide NPPA notification S.O. No. 2730(E) dated 17.08.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Review application dated 16.09.2016
2) NPPA notification under review S.O. No. 2730(E) dated 17.08.2016
3) Record Note of discussions held in the personal hearing held in the matter on 18.10.2016

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. 2730(E) dated 17.08.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of “Imatinib Mesylate 100 mg tablet”.

2. The main grievances of the company are that –
- I. The company has submitted that this has reference to the ceiling price notification SO No. 2730(E) dated 17.08.2016 issued by NPPA. The notification along with the working sheet was displayed on the official website of NPPA on 19.08.2016. The said notification has revised the ceiling price of Imatinib Mesylate Tablets 100 mg at Sr. No. 13. Hereby, they submitted that they are aggrieved by the said notification as the price calculation shown in the working sheet dated 19.08.2016, incorrectly captured our price details. They therefore seek a review of the same under paragraph 31 of DPCO 2013 on the following grounds:
- a. The working sheet showing calculation of ceiling price displayed on the website of NPPA on 19.08.2016. The ceiling price was revised as Rs.71.66 per Tablet.
 - b. Draft working sheet for ceiling price fixation of Imatinib Mesylate was presented on NPPA website on 15.07.2016, and companies were to respond to the office of NPPA in case of any data discrepancy by 10 working days of the draft working sheet publication.
 - c. In draft working sheet, PTR of their product IMALEK 100 mg Tablet 10 was shown captured incorrectly as Rs.700.72 per pack of 10 Tablets, while the prevalent PTR was Rs.772.74 per pack of 10 tablets in August 2015.

- d. They had presented their position through a representation dated 26.07.2016 of the office of NPPA on correcting the PTR with supporting documents. However, their plea was not considered in the ceiling price calculation, evidenced from the working sheet of price notification SO No. 2730(E), showing PTR of IMALEK 100 mg Tablet 10as Rs. 700.72 instead of Rs.772.74 as requested.
 - e. They also enclosed the acknowledged copy of their submission dated 26.07.2016 made to the office of NPPA.
- II. In view of above submission, they requested this Department to kindly issue necessary directives to NPPA to recalculate the ceiling price.

Comments of NPPA:

- (i) NPPA has fixed the ceiling price for **Imatinib Mesylate 100mg Tablet** of Rs. 87.59/tablet vide S.O. 1827(E) dated 21.6.2013 and the same was revised to Rs. 93.13, Rs. 96.71 & Rs. 94.09 per tablet vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011. Under NLEM 2015, the ceiling price for this pack was notified as Rs. 71.66/tablet vide S.O. 2730(E) dated 17.8.2016 under para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013 based on pharmatrac data for August 2015 as per existing practice.
- (ii) **As per information available with M&E division (through IPDMS report), the company is not following ceiling price for subject formulation notified vide S.O. 2730(E) dated 17.8.2016. DOP is also requested to verify the same from the company.**

3. During the personal hearing, the representative of the company submitted that NPPA had uploaded the draft working sheet of Imatinib Mesylate 100 mg tablet on 15th July, 2016, where the PTR of the product Imalek was shown as Rs.700.72 for a pack of 10 tablets. In response to this, company had submitted their representation on 26th July, 2016, stating that the correct PTR of Imalek applicable in the month of August, 2015 was Rs.772.74 for a pack of 10 tablets. Further, company had submitted the invoice copies and copy of controlled samples of Imalek in reply to NPPA's letter dated 23rd August, 2016. Company had submitted Form-V in IPDMS on 9.9.2016 and physically on 14.9.2016 confirming the implementation of the notified ceiling price vide SO 2730(E), dated 17.8.2016.

NPPA representative submitted that NPPA will re-examine the issue after receipt of relevant document/information.

4. **Examination:**

The only grievance of the petitioner company is that the actual PTR of their formulation Imalek 100 mg tablet for a pack of 10 tablets was Rs.772.74, applicable in the month of August, 2015, whereas NPPA has taken the PTR of the product as

Rs.700.72 for a pack of 10 tablets, in the working sheet while calculating the ceiling price of Imatinib Mesylate 100 mg tablet. The company representative also submitted documentary proof in support of their claim. NPPA representative stated that the same will be examined after receipt of relevant document/information.

On going through the calculation sheet, it is observed that the contention of the petitioner company has got merit and needs examination by NPPA. In view of the above, Hearing Authority of the opinion that NPPA may be directed to examine the relevant document/information submitted by the petitioner company and to re-fix the ceiling price of Imatinib Mesylate 100 mg. tablet, on merit.

5. Government Decision:

“NPPA is hereby directed to examine all the relevant documents/information furnished by the petitioner company again and to re-fix the ceiling of Imatinib Mesylate 100 mg tablet, on merit”

Issued on this date, the 15th day of November, 2016.

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

To

1. **M/s. Sun Pharma Laboratories Ltd.,
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. **Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
3. **Technical Director, NIC with the request to upload the review order on the Department's website**