

No. 31015/18/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: Review application of M/s Astellas Pharma India Private Ltd. against price fixation of Tacrolimus capsules (0.5 mg and 1 mg) vide NPPA order No. S.O. 1405(E), dated 12.4.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 03.05.2016
2) NPPA notification under review S.O. No.1405(E), dated 12.4.2016
3) Record Note of discussions held in the personal hearing held in the matter on 30.6.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Astellas Pharma India Private Ltd. (hereinafter called the petitioner) against notification S.O. No.1405(E), dated 12.4.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Tacrolimus capsules (0.5 mg and 1 mg).

2. The petitioner has contended as under:

- (i) They received notification of fixation ceiling price of Tacrolimus capsules via SO 1405(E) published on 12th April 2016. The ceiling price has been fixed at 16.76 INR/capsule for 0.5 mg and 32.18 INR/capsule for 1 mg.
- (ii) Astellas Pharma Inc., who is the innovator of Tacrolimus capsules and Astellas Pharma India Pvt. Ltd. imports and sells the product in India at price that is higher compared to the ceiling price notified.
- (iii) They believed that their Tacrolimus capsules' prices may not have been included for calculating the ceiling price of Tacrolimus capsules.
- (iv) As per Office Memorandum No.19 (714)/2016/NPPA/Div.II dated 11.04.2016, they have submitted a representation against ceiling price of Tacrolimus capsules (0.5 mg and 1 mg) to NPPA. The representation was submitted vide letter Ref. AID/RA/NPPA/001.

They requested this Department for review of ceiling price of Tacrolimus capsules under Para 31 of DPCO, 2013. They have provided following supporting documents:

1. Price to retailer with copy of Invoice Number: 2057 dated 12-08-15
2. Price to retailer with copy of Invoice number: 3008 dated 07-10-15
3. Price to retailer with copy of Invoice number: 337 dated 05-08-15
4. Moving Annual Turnover for Prograf (Tacrolimus) 0.5 mg and 1 mg for August, 2015

3. The contentions of petitioner and the NPPA were heard on 30th June, 2016. During the hearing, the petitioner company did not submit any more submission. NPPA representative submitted that the required documents / information submitted by the company is under examination.

4. **Examination:**

The petitioner company has furnished the copies of invoices in respect of PTR of their product "Prograf (Tacrolimus) 0.5 mg and 1 mg" as well as Moving Annual Turnover for the same. From the computation sheet of NPPA, it is clear that the product of the company has not been considered by NPPA while fixing the ceiling price of the aforesaid product. NPPA representative has stated that the documents/ information submitted by the petitioner company is under examination by them.

In view of the above, NPPA may be directed to consider the data furnished by the petitioner company and re-fix the ceiling price of the product Prograf (Tacrolimus) 0.5 mg and 1 mg as notified vide SO No.1405(E), dated 12.4.2016.

5. **Government Decision:**

NPPA is directed to re-fix the ceiling price of "Tacrolimus capsules (0.5 mg and 1 mg)" after taking into consideration all data, furnished by the petitioner company and available from other sources, on merit, within a period of one month from the date of issue of the Order of Reviewing Authority.

Issued on this date, 30th day of August, 2016.

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

To

1. **M/s.Astellas Pharma India Private Ltd.,
301, 3rd Floor, C and B Square,
Nr. Divine Child High School,
127, Andheri Kurla Road, Chakala, Andheri East,
Mumbai-400 069.**
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**