

No. 31015/35/2016-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 Abbott Healthcare Private Limited against price fixation of “Metronidazole Oral Liquid 200 mg/5 ml” vide NPPA order No. S.O. 1561(E) dated 27.04.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 25.05.2016
2) NPPA notification under review S.O. No.1561(E) dated 27.04.2016
3) Record Note of discussions held in the personal hearing held in the matter on 08.07.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Abbott Healthcare Private Limited (hereinafter called the petitioner) against notification S.O. No.1561(E) dated 27.04.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Metronidazole Oral Liquid 200 mg/5 ml.

2. The petitioner has contended as under:

- i. NPPA has considered Flagyl 200 mg Suspension 100 ml for the purpose of calculating PTR.
- ii. Flagyl 200 mg Suspension 100 ml & Flagyl 200 mg Suspension 30 ml are discontinued long back, now company is manufacturing & marketing only Flagyl 200 mg Suspension 60 ml.
- iii. Therefore, while calculating the ceiling price, Flagyl 200 mg Suspension 100 ml and Flagyl 200 mg Suspension 30 ml should not be considered.
- iv. Company requested to revise the ceiling price of Metronidazole Oral Liquid 200 mg/5 ml.

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 0.25 per ml for Metronidazole Oral Liquid 200 mg/ml notified vide S.O. 1561(E) dated 27/04/2016 based on the Pharmatrac data as per existing practice.

- (ii) Company has not submitted any documentary proof regarding the period of the discontinuation of the manufacturing/ marketing of the subject formulation.
- (iii) Company has been marketing Flagyl 200 mg Suspension 60 ml and PTR of Rs.0.22 has been considered by NPPA while calculating the ceiling price.

3. In the personal hearing held on 08th July, 2016, the representative of the company submitted that the company would provide a Chartered Accountant certificate and duly supported by a covering letter by the authorized signatory, validating their claim that they had discontinued Flagyl 200 mg. Suspension 100 ml. and Flagyl 200 mg. Suspension 30 ml. by the petitioner company prior to DPCO 2013.

4. **Government Decision:**

In view of the above, authenticated documentary proof regarding discontinuation of Flagyl 200 mg. Suspension 100 ml. by the petitioner company prior to DPCO 2013, be examined by NPPA on merits and to refix the ceiling price of the aforesaid formulation of the company, i.e. Metronidazole Oral Liquid 200 mg/5 ml, within one month of the issue of this Order in this regard.

In view of the above, the present review petition stands disposed off.

Issued on this date, the 14th day of September, 2016.

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

To

1. **M/s. Abbott Healthcare Private Limited**
D Mart Bldg.,
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**