

No. 31015/58/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhawan,
New Delhi 110 001

Subject: Review application of M/s Abbott Healthcare Pvt. Limited against price fixation of "Phenytoin 100 mg tablet" vide NPPA order No. S.O. 1816(E)[corrected SO No.1819(E)] dated 18.05.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 10.06.2016
2) NPPA notification under review S.O. No. 1816(E)[corrected SO No.1819(E)] dated 18.05.2016
3) Record Note of discussions held in the personal hearing held in the matter on 23.08.2016.

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 Pvt. Limited (hereinafter called the petitioner) against notification S.O. No. 1816(E)[corrected SO No.1819(E)] dated 18.05.2016] issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Phenytoin 100 mg tablet.

2. The petitioner has contended as under:

1. It has been observed from the working sheet published by NPPA, that NPPA has considered Phenytoin (ZYDUS) Sodium 100mg tablet 100 of Zydus Cadila in the calculation. But we understand that manufacturing of this particular SKU has been discontinued by Zydus Cadila from the last 1-2 years which is evident from very low MAT value of this SKU in the AIOCD data bank.
2. Considering the above facts, they requested this Department to advise NPPA to revise the Ceiling price of Phenytoin 100mg Tablets, at the earliest.
3. They have already implemented the ceiling price as per NPPA Notification S.O. 1861(E) {corrected S.O. no. 1819(E)} dated 18th May 2016 for their SKU Eptoin 100mg Tablets.

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 1.42 / tablet for **Phenytoin 100mg tablet** vide S.O. 1879(E) dated 28.6.2013 and the same was revised to Rs.1.51, Rs.1.57 & Rs.1.53 vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011. The ceiling price for this pack was fixed Rs.1.27/tablet vide S.O. 1816(E) dated 18.5.2016 under NLEM 2015.
- (ii) NPPA has fixed ceiling price Rs. 1.27 per tablet for **Phenytoin 100mg tablet** vide S.O. 1816(E) dated 18.5.2016 are as per para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013 as per data provided by pharma-trac for August, 2015.

- (iii) Company has not submitted any representation to NPPA in this regard.
- (iv) Representation submitted by M/s Zydus Cadila in this regard is under examination.

3. During the personal hearing the representatives of the company submitted to advise NPPA to revise the ceiling price of Phenytoin 100 mg tablet after removing the discontinued pack of Phenytoin (ZYDUS) Sodium 100 mg. tablet pack of 100's of Zydus Cadila.

The representative of NPPA submitted that the representation of M/s Zydus Cadila is under examination. Company's request may be examined after verification from the Pharmatrac.

4. Examination:

In the instant case, the only contention of the petitioner company is that while fixing the ceiling price of **Phenytoin 100 mg tablet**, NPPA has considered Phenytoin (ZYDUS) Sodium 100mg tablet 100 of Zydus Cadila in the calculation, whereas the manufacturing of this particular SKU has been discontinued by Zydus Cadila from the last 1-2 years.

Keeping in view the submission made by the petitioner company, NPPA may be directed to examine the case by verifying from the Zydus Cadila and Pharmatrac, and re-fix the ceiling price, if necessary.

5. Government Decision:

NPPA is hereby directed to examine the case by verifying from Zydus Cadila and Pharmatrac, and to re-fix the ceiling price of Phenytoin 100 mg tablet, on merit.

Issued on this date, the 6th day of October, 2016.

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

To

1. **M/s. Abbott Healthcare Pvt. Limited,**
D Mart Building,
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**