

No. 31015/71/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

.....
B Wing, Janpath Bhawan,
New Delhi 110 001
Dated, the 30th January, 2017

Subject: Review applications of M/s Abbott Healthcare Pvt. Limited against price fixation of their formulations "Phenobarbitone 30 mg and Sodium Valprorate 200 mg tablets" vide NPPA order No. S.O. 2193(E)[corrected SO No.2195] dated 23.06.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review applications dated 20.07.2016
2) NPPA notification under review S.O. No.2193(E) [corrected SO No.2195] dated 23.06.2016
3) Record Note of discussions held in the personal hearing held in the matter on 23.8.2016.

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.2193(E) [corrected SO No.2195] dated 23.06.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Phenobarbitone 30 mg and Sodium Valprorate 200 mg tablets.

2. The petitioner has contended as under:

For Phenobarbitone 30mg :-

- I. They have reviewed the working sheet for the subject ceiling price notification published by NPPA on 28th June'2016 and have observed the below discrepancy :-
 - (i). NPPA had notified upward revision of ceiling price for Phenobarbitone 30mg on 24.02.2016 vide notification no. SO 582(E) as INR 1.63 & SO 644(E) dt. 02.03.2016 as INR 1.59 towards negative WPI reduction
 - (ii) The subject correction in Feb'16 was a result of the review hearing which was filed by us challenging the ceiling price calculation of S.O 1877(E) dated 28.06.2013 & S.O 1785(E) dated 10.07.2014 and finally after a long waiting, NPPA had acknowledged the error and awarded the relief in Feb'16
 - (iii) Hence, based on the Feb'16 ceiling price notification, which overrides the Jun'13/July'14 NPPA notifications, the PTR works out to be INR 1.29 per tablet. Hence applying MAT Aug'15 PTR while refixing ceiling prices in Jun'16, is prone to error due to incorrect base being referred. Hence, for the calculation purpose, NPPA needs to consider PTR as INR 1.29 per tablet

which was recently notified by NPPA after factoring negative WPI. To summarize, the re-fixation of ceiling price again in Jun'16 ignoring the Feb/Mar'16 NPPA notification, has resulted in incorrect calculation and reduction.

For Sodium Valprorate 200mg Tablets.-

- II. It seems there are few calculation errors in the working sheet published by NPPA on 28th June 2016. Here NPPA has considered the PTR for Epilex 200mg Tablets 15's as INR 1.74 per tab whereas they had stopped manufacturing & marketing of Epilex 200mg Tablets 15's pack since year 2011. **Therefore kindly do not consider Epilex 200mg Tablets 15's pack for the purpose of calculation of ceiling price.**
- III. Further NPPA has considered Epilex 200mg Tablets 10's PTR as INR 2.61 per tab, whereas actual PTR should be INR 2.71 per tab.
- IV. Considering the above facts, they requested this Department to kindly advice NPPA to withdraw the ceiling price of Phenobarbitone 30mg Tablets and Valprorate 200mg Tablets (**Epilex 200mg**). Meanwhile, despite the error in calculation, **they have implemented the ceiling price as per NPPA Notification No. SO 2193(E) {corrected S.O. No. 2195(E)} dated 23.06.2016** for their formulations.

3. Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 0.93 / tablet for **Phenobarbitone 30mg tablet** vide S.O. 1877(E) dated 28.6.2013 and the same was revised to Rs. 0.99, Rs. 1.48, Rs. 1.54, Rs. 1.63 & Rs. 1.59 vide S.O. 1156(E), 1785(E), 619(E), 582(E) & 644(E) dated 28.4.2014, 10.7.2014, 26.02.2015, 24.02.2016 & 02.3.2016 respectively under NLEM 2011. The ceiling price for this pack was fixed Rs. 1.12/tablet vide S.O. 2193(E) dated 23.6.2016 under NLEM 2015.
- (ii) NPPA has fixed ceiling price Rs. 3.07 /tablet **Sodium Valprorate 200mg tablet** vide S.O. 1571(E) dated 14.6.2013 and the same has been revised to Rs. 3.26, Rs. 3.39 & Rs. 3.30 vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 under NLEM 2011. The ceiling price for this pack was fixed to Rs. 2.75/tablet vide S.O. 2193(E) dated 23.6.2016 under NLEM 2015.
- (iii) Company has not submitted any representation to NPPA in this regard.

4. During the personal hearing on 23.8.2016, the representatives of the company submitted that while fixing ceiling price of Phenobarbitone 30 mg. tablet, NPPA considered August, 2015 data while NPPA had subsequently notified upward revision of ceiling price for Phenobarbitone 30mg on 24.02.2016 vide notification no. SO 582(E) as INR 1.63 & SO 644(E) dt. 02.03.2016 as INR 1.59 towards negative WPI reduction. Hence, it is requested to advise NPPA to consider 24.2.2016 price notification instead of August 2015 PTR. Invoice copy of May,

2016, evidencing implementation of Rs.1.59 ceiling price after reduction of negative WPI, was officially submitted during the hearing.

As regards **Sodium Valprorate 200mg tablet** –

1. company had stopped manufacturing & marketing of Epilex 200mg Tablets 15's pack since year 2011. The company has submitted CA certificate to this effect to NPPA during personal hearing.
2. Further NPPA has considered Epilex 200mg Tablets 10's PTR as INR 2.61 per tab, whereas actual PTR should be INR 2.71 per tab. Scanned copy of carton submitted during personal hearing.
3. Hence, it is requested to advise NPPA to consider point 1 & 2 above and rework the ceiling price.

NPPA representative submitted that as regards Phenobarbitone 30 mg. tablet, the request of the petitioner company may be examined for consideration of the Authority.

As regards Sodium Valprorate 200 mg tablet, purchase documents submitted by the company may be examined for consideration of the Authority.

5. Examination:

The petitioner company challenged the price calculation for Phenobarbitone 30 mg. against SO 28.6.2013 and SO 1785(E) dated 10.7.2014 and the company was awarded the relief in February,2016 and upward revision of ceiling price for the said formulation was given as Rs.1.63/tablet vide SO 582(E), dated 24.2.2016 and Rs.1.59/tablet (towards negative WPI reduction) vide SO 644(E), dated 2.3.2016. The company's grievance is that NPPA took the MAT August,2015 PTR while fixing ceiling price in June, 2016, instead of taking the revised ceiling price granted to them in February/March, 2016. Hence, the contention of the petitioner company that taking MAT August,2015 PTR and ignoring February/March, 2016 price fixation by NPPA, while fixing ceiling price in June, 2016 has got merit. Therefore, NPPA may be directed to reconsider the fixation of ceiling price for Phenobarbitone 30 mg. tablet.

As regards, Sodium Valprorate, company stated that the manufacturing & marketing of Epilex 200mg Tablets 15's pack have been stopped since year 2011 and also submitted CA certificate to this effect. Further, NPPA considered Epilex 200mg Tablets 10's PTR as INR 2.61 per tab, whereas actual PTR should be INR 2.71 per tab. In support, the company submitted scanned copy of carton during personal hearing. Keeping in view the documents submitted by the company, NPPA may be directed to examine the documents submitted by the petitioner company on merit, and refix/revise the price of Sodium Valprorate, if necessary.

6. Government Decision:

NPPA is hereby directed to refix the ceiling price for Phenobarbitone 30 mg. tablet using revised prices. NPPA is also directed to examine the

documents submitted by the petitioner company on merit, and refix/revise the price of Sodium Valprorate, if necessary.

Issued on this date of 30th day of January, 2017.

**(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**