

No. 31015/38/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s Abbott Healthcare Pvt. Limited against price fixation of their formulation "Phenytoin - 30mg/5ml" vide NPPA order No. S.O. 442(E), dated 14.2.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 09.03.2017
2) NPPA notification under review S.O. No. 442(E), dated 14.2.2017
3) Record Note of discussions held in the personal hearing on 23.5.2017.

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.442(E), dated 14.2.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Phenytoin - 30mg/5ml.

2. The petitioner has contended as under:

(i) They had already made our review petition representation dated 09.01.2017 to NPPA, wherein they have mentioned that the draft working sheet for ceiling price calculation of Phenytoin-30mg/5ml (vide 8(35)/2016/DP/NPPA/Div II dated 17.11.2016) were bearing anomaly in calculation.

(ii) NPPA has considered PTR as Rs. 54.48 per bottle of for Eptoin 30mg Suspension 200ml of M/s Abbott India, where as the correct PTR of Aug'15 is Rs. 59.81. (PTR per ml is Rs. 0.30).

(iii) Company further submitted that the Review petition of CP of Phenytoin 100mg Tablets is pending with NPPA, hence the percentage considered for reduction under monopoly of Phenytoin is not correct.

(iv) Company appealed to the authority to advise NPPA to correct the apparent variance in calculation.

3. **Comments of NPPA:**

1. The ceiling price of Rs. 0.27/ml for **Phenytoin 30mg/5ml oral liquid** was notified vide S.O. 442(E) dated 14.02.2017 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

2. Company has stated that correct methodology was not followed in arriving at the ceiling price for **Phenytoin 30mg/5ml oral liquid**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has stated that they have submitted representation against Draft working sheet and the same was not considered by NPPA.	NPPA has considered the representation submitted by the company but the representation not conclusively proved, hence rejected.
2.	Company has pointed out that NPPA has not considered actual PTR for their product Eptoin 30mg Suspension 200ml. Company has stated that NPPA has considered PTR 54.48 against the actual PTR 15.81.	NPPA has considered the PTR as per data provided by PharmaTrac for the period of August, 2015.
3.	Company has also pointed out that NPPA has to re- fixed the ceiling price of Phenytoin 100mg Tablet based on review order No. 31015/58/2016 dated 6.10.2016.	NPPA has revised the ceiling price RS. 1.47/ tablet (including the impact of WPI vide S.O. 1010(E) dated 30.03.2017)

3. Company has not challenged any notification in respect of **Phenytoin 30mg/5ml oral liquid** in the Court.

4. During the personal hearing, the representatives of the company submitted documentary proof in support of correct PTR of Phenytoin 30mg/5ml oral liquid, i.e. Rs.59.81, whereas in the calculation sheet, it is shown as Rs.54.48.

Further, the company representatives also brought to the notice that NPPA had issued a notification No.SO 1010(E) 30.3.2017, based on the review order of DoP with respect to Phenytoin 100mg tablet, which was notified by NPPA subsequently. The monopoly calculation should therefore be corrected / revised taking into account the notified price vide SO 1010(E), dated 30.3.2017.

NPPA representative stated that the issue may be looked into on submission of documents by the company.

5. **Examination:**

The main contention of the petitioner company is that NPPA has not considered the actual PTR of their formulation Eptoin 30mg Suspension 200ml while fixing the ceiling price of Phenytoin 30mg/5ml oral liquid. According to petitioner company, the actual PTR of their formulation Eptoin 30mg Suspension 200ml is Rs.59.81 whereas NPPA has considered PTR of Rs.54.48. In support of their claim, the company has submitted documentary proof to NPPA, a copy of which was submitted to this office at the time of hearing. In view of this it is proposed that NPPA may be directed to consider re-fixing/revising the ceiling price of Phenytoin-30mg/5ml after examining information/documentary proof in support of their claim about actual PTR of formulation Eptoin 30mg Suspension 200ml, subject to confirmation from Pharmatrac, on merit.

5.2 Company further stated that a review petition was filed on 10.6.2016 against price fixation of "Phytoin 100mg tablets" notified by NPPA vide SO 1819(E), dated 18.5.2015. DoP, after examining the review petition, issued Review Order No.31015/58/2016-PI.I, dated 6th October, 2016, directing NPPA to re-fix the CP of the subject formulation. Based on the

review order, the NPPA re-fixed the ceiling price of Phytoin 100mg tablets vide SO 1010(E), dated 30.3.2017, i.e. after notifying the ceiling price of Phenytoin-30mg/5ml.

5.3 On perusal of calculation sheets of SO 1819(E), dated 18.5.2015 and SO 1010(E), dated 30.3.2016, the NPPA has taken into account PTR of 6 and 5 formulations respectively instead of 4 formulations having more than 1% market share. It is proposed that NPPA may be directed to first revise the ceiling price of Phenytoin 100mg tablet (fixed vide SO 1819(E), dated 18.5.2015 and revised vide SO 1010(E), dated 30.3.2016), considering formulations having more than 1% market share and thereafter correct / revise the average reduction percentage in monopoly calculation under para 6 of DPCO, 2013, taking into account the revised reduction percentage of subject formulation.

Government decision:

“NPPA is directed to take into account the correct ceiling price of Phenytoin 100mg tablet as revised vide S.O. 1010(E), dated 30.3.2016, in the calculation sheet for percentage reduction under monopoly condition.”

“NPPA is further directed to hear the petitioner and examine the relevant documents furnished by them in support of their claim about actual PTR of Eptoin 30mg Suspension 200ml, i.e. copies of sample invoices to retailer and samples of August, 2015, and after verification, to refix the ceiling price of Phenytoin – 30mg/5ml, on merit.”

“Thereafter NPPA to correct the average reduction percentage in monopoly calculation under para 6 of DPCO, 2013, taking into account the revised reduction percentage of subject formulation.”

“The above directions be implemented within a period of thirty days from the date of issue of this order and compliance report be submitted.”

Issued on this date of 9th day of February, 2018.

(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**