

No. 31015/34/2018-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

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A Wing, Shastri Bhawan,  
New Delhi 110 001

Order

1. This is an order disposing of an application dated 28.05.2018, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Abbott Healthcare Private Limited (hereinafter called the applicant) against notification S.O. No.1768(E), dated 26.04.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Phenytoin - 30mg/5ml.

2. The company has contended as under:

(i) DoP's review order no. 31015/38/2017 dated 09/02/2018 clearly states that "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 200 ml, i.e. copies of sample invoices to retailer and samples of August, 2015, and after verification, to refix the ceiling price of Phenytoin – 30 mg/5ml, on merit."

(ii) Minutes of 188<sup>th</sup> authority meeting held on 23/04/2018 also mentioned that as far as correct PTR is concerned Pharmatrac has confirmed that the correct PTR is seen in August, 2015 but is not the highest count.

(iii) It is evident that the price has been changed from September 2015 onwards, and there must be enough entries in July and August 2015 evidencing price increase. The company has also submitted more than 1000 bills as summary of invoices for August, 2015.

(iv) Ceiling price under NLEM was fixed on the 2<sup>nd</sup> December, 2013 vide S.O. 3562(E) considering monopoly reduction of 10.68%. Para 6 does not provide that monopoly to be applied every time the price is fixed. It needs to be applied only one time as there is already a reduction while fixing the ceiling price under NLEM 2011.

(v) Company again submitted the list of invoices along with pack shots of the formulation for August, 2015.

3. Comments of NPPA:

3.1 NPPA has correctly notified the ceiling price of subject formulation as Rs 0.29 per ml vide SO 1678 (E) dated 26.04.2018. As far as PTR is concerned reference is invited to Department of Pharmaceutical review order NO 31015/16/2018-Pricing dated 26.06.2018, for M/s Sun Pharma Laboratory Limited against S.O. 269 (E) dated 16.01.2018, wherein Department of Pharmaceutical has upheld the consideration of the

PTR of the formulation of the company, which is in highest count, for ceiling/retail price calculation and considered it as a logical and correct decision.

3.2 Hence issues raised by the company have no merit and application may be rejected at the admission stage itself.

3.3 NPPA informed that company is following the notified ceiling price for the formulation.

5. Examination:

5.1 NPPA refixed and notified the ceiling price of formulation Phenytoin 30mg/5ml vide SO 1768(E), dated 26.4.2018 in compliance to DoP's review order No. 31015/38/2017 dated 09/02/2018.

5.2 NPPA considered the PTR of Rs.54.48 per bottle of Eption 30mg Suspension 200ml, based on Pharmatrac data, being on highest count. The company claimed that their said product with PTR of Rs.59.81 (PTR per ml Rs.0.30) was having enough entries in the months of July and August, 2015 evidencing price increase. In support of its claim, the company submitted more than 1000 bills as summary of invoices for August, 2015.

5.3 The PTR of Rs.54.48 per bottle reflects maximum count of 223 in comparison to count of 169 of the PTR of Rs.59.81 per bottle of the company. In view of this, considering the PTR of Rs.54.48 per bottle being the highest count, as reported by Pharmatrac data and considered by NPPA, is a logical and right decision. Therefore, the request of the company to consider the PTR of Rs.59.81 per bottle cannot be considered and the review application be rejected.

5.4 As regards the issue of again applying monopoly reduction, the company, in its additional submissions, itself stated that the same has been resolved and company do not wish to pursue the same.

6. Decision:

“Considering the PTR of the formulations (of a company), which is of the higher count (223), for ceiling/retail price calculation is a logical and right decision. Therefore, the request of the company about considering the PTR of a lower count (169) of Rs.59.81 per bottle of their product Eption 30 mg suspension 200 ml, as on August, 2015, for fixing the retail price of Phenytoin – 30 mg/5ml, cannot be accepted being on less count.”

Issued on this date of 8<sup>th</sup> day of October, 2018.

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

Copy to :-

1. M/s. Abbott Healthcare Private Limited, 3-4, Corporate Park, Sion Trombay Road, Mumbai-400071.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS (C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website