

**No.31015/40/2023-Pricing (E-23352)**  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

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Room No. 340-B, A Wing, Shastri Bhawan,  
New Delhi-110 001.

**Order**

M/s Abbott India Limited (hereinafter called the “Applicant”) filed a Review Application dated 09.02.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 194(E) dated 11.01.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of “Apnicaf 20 mg oral solution 1.5 ml” containing Caffeine Oral liquid 20 mg/ml.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 02.06.2023 and presented their respective logics.

**3. Major contentions raised by the Applicant:**

It was contended, on behalf of the Applicant, that NPPA has erred in determining the ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 “Caffeine Oral liquid 20 mg/ml / Apnicaf 20mg oral solution 1.5ml” were included in the revised Schedule-I of the DPCO, 2013 notified on 11<sup>th</sup> November, 2022. Hence, the formulation “Apnicaf 20mg oral solution 1.5ml was also included in the draft calculation of ceiling price under the provision of para 4,6,10,11, 14 ,16, 17 and 18 of DPCO 2013.

3.2 Though other manufacturers of Caffeine Oral liquid 20 mg/ml had implemented the WPI under Para 16 of DPCO 2013 between April 2022 to July 2022 respectively, incorrect Price-to-Retailer (PTR) data of the brand ‘Capnea 20mg Oral Solution 2ml’ of M/s Cipla Ltd. was considered for the purpose of fixing of ceiling price of Caffeine Oral liquid 20 mg/ml which resulted in a lower ceiling price being fixed. The same was proven to NPPA by the Applicant through submission of representation (reference AL/2022/12/09 dated 26.12.2022), which was made within prescribed time period of 10 working days.

3.3 Pharmarack report for the month of September 2022 eventually reflected the revision in MRP for the formulation ‘Capnea 20mg Oral Solution 2ml’ of M/s Cipla

Ltd. Therefore, the ceiling price of Caffeine Oral liquid 20 mg/ml should have been fixed after considering the revised PTR for the aforesaid product mentioned as follows:

Sr.	No Competitor Product Name	Company Name	PTR Considered	PTR should be Considered
1.	Capnea 20mg Oral Solution 2ml	Cipla Ltd.	389.33	425.81

3.4 A delay in the implementation of revised MRP or PTR based on WPI impact should not be construed as non-implementation of WPI based revision. Non-reflection/delayed reflection of PTR in the market-based data provided by Pharmarack should not be construed as non-implementation of revised MRP, especially when pack shots of the relevant month are provided as documentary evidence in support of price revision.

#### 4. Gist of clarifications made by NPPA:

NPPA on the other side argued that the instant review is not tenable on the following grounds:

4.1 As per the provisions of DPCO [Para 16(2)], the manufacturers may increase the MRP of scheduled formulations once in a year, in the month of April on the basis of WPI. Further, as per para 16(3), information about the revision, if carried out, shall be forwarded to the Government in Form-II within a period of 15 days of such revision. This implies that Form-II for price revision based on WPI may be submitted latest by 15<sup>th</sup> May. Accordingly, NPPA has considered price revision in all cases where any representation is received and Form II/V has been filed by the company on or before 15<sup>th</sup> May, 2022.

4.2 The draft working sheet uploaded on NPPA's website on 13.12.2022 was having 4 line items. The Applicant filed representation dated 26.12.2022 requesting to correct the PTR of 3 line items except "Capnea 20mg Oral Solution 2ml" of M/s Cipla Limited. The PTR of these 3 line items for which the Applicant had filed representation were corrected as Form-V and Form-II for these were submitted by the companies within the permissible time-line.

4.3 Further, w.r.t. "Capnea 20mg Oral Solution 2ml" of M/s Cipla Limited, neither the Applicant nor M/s Cipla represented for revision of PTR. Also, M/s Cipla Ltd. did not file Form-II and Form-V with NPPA in respect of 2ml pack. Hence, the price revision has not been considered.

4.4 Therefore, NPPA has taken correct PTR for brands "Capnea 20mg Oral Solution 2ml" for ceiling price calculation of the formulation 'Caffeine Oral Liquid 20mg/ml' as available in market based data i.e. Pharmarack database.



## 5. Examination:

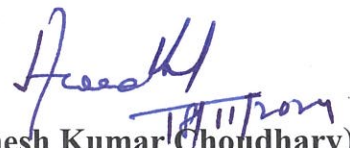
5.1 In fixing the ceiling price of Scheduled formulations, NPPA has followed the due provisions of DPCO. Thus, NPPA has taken due cognizance of the provisions under Para 16(2) and 16(3) of DPCO, 2013 which provides that manufacturers may avail the increase in MRP of scheduled formulations once in a year, in the month of April, on the basis of the WPI; and, that such information about the revision, if carried out, shall be forwarded to the Government on IPDMS in Form-II and Form-V within a period of fifteen days. DPCO also expressly maintains that non-submission of information under Para 16(3) shall be construed as non-revision of MRP.

5.2 Accordingly, NPPA has taken the relevant prices for fixing the ceiling price of the subject formulation as per the extant provisions of DPCO, 2013.

## 6. Decision:

The action of NPPA fixing the ceiling prices of the subject formulation is as per the provisions of DPCO, 2013 and is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 18<sup>th</sup> day of November, 2024.



(Awadhesh Kumar Choudhary)

Sr. Economic Adviser to the Government of India  
[For and on behalf of the President of India]

To,

M/s Abbott India Limited  
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## Copy to:

1. Chairperson, NPPA, New Delhi.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi.
3. Technical Director, NIC for uploading the order on DoP's Website.
4. Guard File.