

No. 31015/1/2017-PI.I  
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 Cipla Ltd. against price fixation of “Ibuprofen Oral Liquid 100 mg/5 ml” vide NPPA order No. S.O. 4128(E), dated 22.12.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application dated 19.01.2017  
2) NPPA notification under review S.O. 4128(E), dated 22.12.2016  
3) Record Note of discussions held in the personal hearing held in the matter on 28.02.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Cipla Ltd. (hereinafter called the petitioner) against notification S.O. No.4128(E), dated 22.12.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Ibuprofen Oral Liquid 100 mg/5 ml.

2. The petitioner has contended as under:-

- I. The worksheet for calculation of ceiling price of formulations notified vide S.O. 4128(E) dated 22<sup>ND</sup> December, 2016 failed to consider other manufacturers of the aforesaid formulation inter-alia including “BRUFEN SUSP” as manufactured and marketed by Abbott India Ltd.
- II. **AND WHEREAS, the company hereby submits independent data from IMS to certify that Brufen Susp has Moving Annual Turnover (MAT) for the period ending August 2015 of greater than 1% Market Share. NPPA has erred by considering pack sizes which have never been sold by our company namely: 30ml, 50ml and 500ml. These pack sizes do not exist in the market and need to be excluded from the calculation of ceiling price as per Para 4 of DPCO, 2013.**
- III. Company further submitted that **NPPA has also erred by considering “IBUGESIC 100 MG SUSP” – 60 ml pack which has been discontinued by our company since March 2015. Thus, NPPA must excluded the 60ml pack size from the calculation of ceiling price as per Para 4 of DPCO, 2013 for Ibuprofen Oral Liquid 100mg/5ml.**
- IV. **AND WHEREAS, NPPA has further erred by not considering their existing formulation namely: “IBUGESIC 100 MG SUSP” – 100 ml pack which was being sold by our company at a PTR of INR. 17.60 and corresponding MRP of INR.**

22.86. They also submitted a copy of the invoice of August, 2015 and duly filed form V – price list for the formulation.

- V. **AND WHEREAS, Para 4 of DPCO, 2013 clearly states that the government shall include the market shares of only generics/ Brands SKU-wise and not Company wise MAT percentages to fix the ceiling prices.** AND WHEREAS, NPPA has further erred by considering their formulation “IBUGESIC 100 MG ORAL SUSPENSION 500 ML” having market share of less than 1% in the calculation of ceiling price for the aforesaid formulation.
- VI. Company has submitted that Under the circumstances:
- a. NPPA should revise the ceiling price for IBUPROFEN ORAL LIQUID 100MG/5ML under the provisions of Para 4 of DPCO, 2013.
  - b. NPPA must consider all formulations having Market share greater than 1% based on MAT of August, 2015 inter-alia including the relevant pack size of Ibugesic as marketed by Cipla and Brufen Susp as marketed by Abbott India Ltd.
  - c. All pack sizes/SKUs having Market share less than 1% must not be considered in the calculation of ceiling price under Para 4.
  - d. All discontinued and inexistent pack sizes/SKUs of any company must be excluded from the calculation of ceiling price under Para 4.
  - e. As there would be a reduction in ceiling price upon correct calculation of ceiling price under para 4, NPPA cannot apply the provisions of Para 6 and notify a Monopoly based ceiling price for the aforesaid formulation.
- VII. Company submitted that having been aggrieved by the fact that the captioned formulation was notified price under Para 6 instead of Para 4, NPPA has committed an error of principal and to maintain equity of justice, the ceiling price of Ibuprofen Oral liquid 100MG/5ML should be calculated considering the provisions of Para 4 of DPCO, 2013.
- VIII. In view of above, company requested this department:-
- a. To consider and conclude that NPPA had erred in pricing of Ibuprofen oral Liquid 100MG/5ML under Notification no. S.O 4128 (E) dated 22<sup>nd</sup> December, 2016.
  - b. To direct NPPA to calculate ceiling price of Ibuprofen oral Liquid 100MG/5ML under the provisions of Para 4 and not Para 6 of DPCO, 2013.
  - c. Pass a speaking order in respect hereof.
  - d. Any other order in interest of this manufacturer.

Comments of NPPA:

In this regard, it is stated that:-

Sl. No.	Company Grievances	NPPA comments
1.	NPPA has considered PTR and MAT value of Ibuprofen Oral Liquid 100mg/ml in pack size 30ml, 50ml & 500ml for calculating the ceiling price. These pack sizes do not exist in the market and need to be excluded from the calculation of ceiling price as per para 4 of DPCO, 2013.	NPPA fixed the ceiling price as per the data provided by pharma-trac for the month of August, 2015 and as per the decision taken in 27 <sup>th</sup> Authority meeting held on 29.3.2016.
2.	NPPA has also considered PTR and MAT value of their brand IBUGESIC 100MG Suspension – 60ml pack which has been discontinued since March 2015.	Company did not discontinue their brand IBUGESIC 100MG Suspension – 60ml pack as per para 21 of DPCO, 2013
3.	NPPA has not considered PTR Rs. 17.60 for IBUGESIC 100MG Suspension – 100ml pack in order to arrive at the ceiling price for this formulation	DOP vide letter no. F. No. 31015/44/2016-PI.I dated 11.7.2016 gave the following, directions: <i>“NPPA to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceuticals firms. Only after taking into account the comments or any additional data thus received within the given time period, the NPPA shall finalize the Ceiling and the Retail Prices. This issues with the approval of Hon’ble Minister (Chemicals &amp; Fertilizers)”</i> . Accordingly, NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. <b>M/s Cipla Limited <u>did not make any representation against the proposed ceiling price uploaded on NPPA’s website.</u></b>

4	Company has pointed out that NPPA shall include the PTR/ market shares of only generics/brands SKU-wise and not company wise MAT percentages to fix the ceiling prices and submitted the copy of review order no.31015/40/2015-PI.I dated 29.11.2016 in support of their claim.	NPPA followed the existing practice in fixing the ceiling price as per the decisions of 27 <sup>th</sup> Authority meeting held on 29.3.2016
5	Company has stated that inclusion of PTR of IBUGESIC 100MG Suspension – 500ml pack is not as per the provisions para 4 of DPCO 2013	NPPA followed the existing practice in fixing the ceiling price as per the decisions of 27 <sup>th</sup> Authority meeting held on 29.3.2016
6	Company is of the opinion that NPPA can not apply the provision of para 6 while fixing the ceiling price considering monopoly situation.	NPPA has fixed the ceiling price as per the provisions of DPCO 2013 as Ibuprofen based formulations were included under DPCO 1995 also.

3. During the personal hearing on 28.02.2017, the representatives of the company submitted that the ceiling price as notified under the provisions of para 6 must be deemed as ultra virus since a ceiling price calculation under para 4 of DPCO 2013 leads to a price reduction. NPPA has failed on two counts with respect to calculation of ceiling price for the aforesaid formulation:-

- (i) Brufen suspension as manufactured and marketed by Abbott India Ltd. contains Ibuprofen Oral liquid 100mg/5ml as notified vide SO 4128(E), dated 22.12.2016 and has greater than 1% market share. Yet, the said formulation of Abbott India Ltd. was not covered in the calculation sheet.
- (ii) NPPA has also erred by considering pack sizes which have never been sold by our company namely, 30ml, 50ml and 500 ml. These pack sizes do not exist and need to be excluded from the calculation sheet.

In view of the above, the company has duly submitted its invoices for the month of August, 2015, as requested. Thus the company requested that the ceiling price of Ibuprofen Oral Liquid 100 mg/5ml should be calculated under the provisions of para 4 of DPCO 2013.

On the issue regarding inclusion/exclusion of brands having 1% or more, NPPA representative further stated that they have been following the existing practice in fixing the ceiling price as per the decisions of 27<sup>th</sup> Authority Meeting of NPPA held on 29.03. 2016. NPPA also stated that even after NPPA uploaded the draft working sheet in its website prior to notification of ceiling price to seek representation from the aggrieved companies based on the DOP's letter no. F.No. 31015/44/2016-PI.I dated 11.7.2016, M/s Cipla Ltd. did not make any representation

at that time. NPPA representative further stated that NPPA may re-examine the issue of inclusion/ exclusion of various brands/ products after receipt of relevant document/information and verification of the same.

**4. Examination:**

The petitioner company has challenged the NPPA S.O. 4128(E), dated 22.12.2016 for price fixation of their formulations **Ibuprofen Oral Liquid 100 mg/5ml** and the main contention of the company is that while fixing the ceiling prices of the aforesaid formulations only those brands that have more than 1% market share have to be considered.

On examination, it is found that NPPA has erred in calculating ceiling price as per para 4 of DPCO, 2013, which clearly mentions that the medicines having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine are to be considered for calculation. The principles applied by NPPA on the basis of decision of their 27<sup>th</sup> Authority Meeting go beyond what is mentioned in DPCO. Hence, NPPA may be directed to refix the ceiling price in accordance with the provisions of DPCO. The DPCO does not recognise a company for average PTR but only medicines/ formulations. Thus, only those formulations are to be considered, which are having MAT value of more than 1% market share. On going through the calculation sheet of the formulation, it is observed that the number of formulations, which are to be considered having more than 1% market share and number of formulations to be excluded, is as per table given below:-

<u>Formulation name</u>	<u>Number of brands to be considered having more than 1% market share</u>	<u>Number of brands to be excluded</u>
<b>Ibuprofen Oral Liquid 100 mg/5ml</b>	3	2

The contention of the company that BRUFEN SUSP as manufactured and marketed by Abbott India Ltd. should have been considered having greater than 1% market share. The petitioner company further submitted that all discontinued and inexistent pack sizes/SKUs of any company must be excluded from the calculation of ceiling price under para 4. During the personal hearing, the company stated that, in support of their claim, the invoices for BRUFEN SUSP of the month of August, 2015 have been submitted. Keeping this in view, the NPPA may be directed to re-examine the issue of inclusion/exclusion of various brands/products after receipt of relevant document/information on merit and re-fix/revise the ceiling price accordingly.

In view of the above, NPPA may be directed to refix the ceiling prices of **Ibuprofen Oral Liquid 100 mg/5ml** by considering only those medicines /

formulations having MAT value of more than 1% market share. Further, NPPA may be directed to re-examine the issue of inclusion/exclusion of various brands/products after receipt of relevant document/information on merit and re-fix/revise the ceiling price accordingly.

5. Government Decision:

**“NPPA is hereby directed to re-fix the ceiling price of the formulation Ibuprofen Oral Liquid 100 mg/5ml by excluding the PTR and MAT value of formulations having less than 1% market share.**

**Further, NPPA is hereby directed to re-examine the issue of inclusion/exclusion of various brands/products after receipt of relevant document/information on merit, and re-fix/revise the ceiling price accordingly.”**

Issued on this date, the 18<sup>th</sup> day of April, 2017.

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

To

1. M/s. Cipla Ltd.,  
Cipla House, Peninsula Business Park,  
Ganpatrao Kadam Marg,  
Lower Parel,  
Mumbai-400013.
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