

No. 31015/66/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhawan,
New Delhi 110 001

Subject: Review application of M/s Micro Labs Limited against price fixation of "Paracetamol 500 mg. tablet" vide NPPA order No. S.O. 1351(E)[corrected SO No.1951(E)] dated 02.06.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 28.06.2016
2) NPPA notification under review S.O. No. 1351(E)[corrected SO No.1951(E)] dated 02.06.2016
3) Record Note of discussions held in the personal hearing held in the matter on 22.09.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Micro Labs Limited (hereinafter called the petitioner) against notification S.O. No. 1351(E)[corrected SO No.1951(E)] dated 02.06.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Paracetamol 500 mg tablet.

2. The petitioner has contended as under:

I. Para 4 of DPCO 2013 states as under:-

4. Calculation of ceiling price of a scheduled formulation.– (1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under: First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:

Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine 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) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

II. That para 2(c) of DPCO, 2013 provides definition of "Brand" which is reproduced below-

(c) "**brand**" means a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as distinct from those of other sellers;

III. They further submitted that neither the PTR nor the basket of producers has changed but the above reduction has been brought about without any assignable reasons by NPPA.

The prices for Paracetamol Tablets of the said strength were changed on the following dates, and the following ceiling prices were announced:

June 14, 2013	Rs. 0.94 per tab
April 28, 2014 (WPI@6.32%)	Rs. 1.00 per tab
February 26, 2015 (WPI@3.849%)	Rs. 1.04 per tab
April 2015 (adjusting for ED)	Rs. 1.036 per tab
March 02, 2016 (WPI@-2.7105%)	Rs. 1.01 per tab
June 2, 2016	Rs. 0.83 per tab

IV. PTR cannot change overnight and in the instant case MAT Values and brands taken in to consideration do not reflect the correct position and NPPA is supposed to verify facts before working out prices. They highlighted the following for this Department's consideration:

- a. For the purpose of calculation even a 1000 jar pack has been considered for calculation of average PTR per tablet. This is a dispensing pack and not a consumer pack and the objective of both type pack is different and cannot be clubbed together. When NPPA itself is clearly differentiating packing charges for "tablets packed in random" and "tablets packed in strip" and also packing material costs of both type of packs are different, how is it possible to compare the price of both for average cost. There is no rational of such an average. The manpower requirements, and packing material cost is vastly different for packing 1000 tablets in jar and 1000 tablets in blisters of 10 x 10 and these aspects cannot be ignored.

Average PTR& ceiling prices for Paracetamol tablets in strips & bulk pack.

	PTR Total	No. of packs	Average PTR	16% Margin	Ceiling price (Excl Tax)	WPI @ 2.7105 %	Final Ceiling Price (excl Tax)
Strip	9.90	112	0.83	0.13	0.96	-0.03	0.93
Bulk	1.09	3	0.36	0.06	0.42	-0.01	0.41
Ceiling price revised by NPPA (Strip + bulk)	10.99	15	0.73	0.12	0.85	-0.02	0.83
Different in ceiling price between strip & Ceiling price revised by NPPA (Strip +Bulk)							0.10

- b. they also enclosed workings of 4th June, 2013 and workings of 2nd June, 2016. How the price can come down after three years when costs have gone up is really disturbing and there cannot be an average PTR of unlike. First IMS Health MARG data was used in June, 2013 as per policy directive, later NPPA of its own switched to Pharmatrac data leading to inconsistencies. **They have uploaded Form V electronically in IPDMS and are following the ceiling price revised by NPPA.**

- V. They further submitted that the working sheet of calculation of ceiling price of Paracetamol Tablets 500 mg is erroneous and not based on the provisions as contemplated under Para 4 of DPCO, 2013.
- VI. They requested this Department to direct NPPA to rework and notify the correct ceiling price of Paracetamol Tablets 500 mg.

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 0.84/tablet vide S.O. 1555(E) dated 14.6.2013 and the same was revised to Rs. 1.00, Rs. 1.04 & 1.0 per tablet vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011 and Rs. 0.83/tablet vide S.O. 1351(E) dated 02.6.2016 under NLEM 2015. Price fixation is correct and company's contention be rejected. Copy of the minutes of the Authority meeting attached.
- (ii) As per information available with M&E division (through IPDMS report), company is no following ceiling prices notified vide S.O. 1351(E) dated 02.6.2016 for above mentioned formulations. DOP is also requested to verify the same from the company by insisting on verified copies of the control sample of price revision and relevant invoices in support.

3. During the personal hearing, the representatives of the company, in addition to the written submissions, further submitted as follows :-

Company submission

The ceiling price was revised on 2-6-2016 vide powers conferred under para, 4,10,11,14,16, 17 and 18 of DPCO, 2013 . Para 10 is not applicable for the notification of this product as this product was not included in DPCO 1995.

NPPA clarification

The representative of NPPA clarified that this is a general practice to mention the above paras while issuing the ceiling price notification.

Company submission

Further, Para 17 is not applicable for the notification of the product as the said product was included in NLEM 2011 and continued to be included in NLEM 2015. As regards, para 18 is concerned, it is applicable for such product where revision has taken place due to basis of moving annual turnover. It is not clear whether revision has taken place because of sub para (i) or sub para (ii) or sub para (iii) of para 18 . There is no transparency in this regard. It is also not clear whether NPPA has collected any data pertaining to MAT value in respect of sub para (ii) or sub para (iii) of para 18.

Para 18 has to be read with Para 17 of DPCO, 2013. Para 17 clearly stipulates that Ceiling price for the Medicines "added" in the first Schedule has to be fixed and not for the products which are already included in Schedule-I. Therefore the notification issued on 2-6-2016 is erroneous.

NPPA clarification

Para 17 deals regarding amendment of the list of scheduled formulations. NPPA shall fix the ceiling price under para 18 for the formulations mentioned in amended list of scheduled formulations.

Company submission

Revision of ceiling price cannot be done once due to Annual Wholesale price index and again by applying para 18 in the same year for the said formulation.

NPPA clarification

There is no merit in the company's submission.

Company submission

The company representative further stated that they have done survey of Pacimol tablet manufactured by IPCA Laboratories Pvt. Ltd. in various retail outlets in Bangalore and they have not found the said pack. Therefore, it is not known as to how Pharmatrac has taken into account the MAT value of the said pack.

Paracetamol tablets in 1000's pack dispensed / supplied to the consumers will not have the batch number, date of manufacture, date of expiry, and the MRP on the dispensed / supplied tablets. Therefore, the very purpose of DPCO 2013 to ensure the supply of scheduled formulation at the price fixed by the Authority is defeated. PTR of unequal packs should not be taken into account.

NPPA clarification

Large pack-size of the scheduled formulations are also available in the shops. NPPA has considered the PTR and MAT value, while fixing the ceiling price for scheduled formulations as submitted by Pharmatrac for the period of August, 2015 as per the existing practice.

The company representative prayed that NPPA may be directed to rework and notify the correct ceiling price for the subject formulation.

4. Examination:

In the instant case, as regards the contention of the petitioner company that the price of paracetamol tablets 500 mg. was revised as Rs.1.01/tablet on 2.3.2016 and again fixed at Rs.0.83/tablet vide SO 1951(E), dated 2.6.2016, **Para 18(i) of DPCO 2013** clearly states that the revision of ceiling prices on the basis of moving annual turnover value shall be carried out **“as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier.”** In view of this, **NPPA has revised the ceiling prices of the formulations strictly as per**

the provision of DPCO 2013. WPI impact has to be taken care of while fixing the ceiling prices. Therefore, the petitioner company has no merit in this contention.

As regards, considering different size of packs, para 4 of DPCO, 2013 clearly states that PTR of brands and generic versions of the medicines having market share more than or equal to one percent of total turnover on the basis of moving annual turnover is considered with fixing the ceiling price. There is no provision for considering different size of packs in DPCO, 2013. Hence, the contention of the petitioner company has got no merit.

In view of the above, the hearing authority is of the view that the contentions of the petitioner company have no merit, hence the review petition may be rejected.

5. **Government Decision:**

“In view of the above, the petition of the company with regard to withdrawal of notification of ceiling price of Paracetamol 500 mg. tablet vide SO 1351(E)[corrected SO No.1951(E)] dated 02.06.2016 stands rejected”.

Issued on this date, the 15th day of November, 2016.

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

To

1. **M/s. Mico Labs Limited,
27, Race Course Road,
Bangalore-560 001.**
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**