

No. 31015/65/2016-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 "Amlodipine tablets" vide NPPA order No. S.O. 1686(E), dated 09.05.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 08.06.2016
2) NPPA notification under review S.O. No. 1686(E), dated 09.05.2016
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. 1686(E), dated 09.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Amlodipine 5 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. After perusal of the working sheet, it is observed that NPPA has also considered Almip 5 mg tablets 10' pack "brand" of M/s Cipla where SKU wise MAT value mentioned is 0.04% (Sl.No.11), as one of the products (different "brand") to

calculate Ceiling price of Amlodipine Tablets 5 mg even though their MAT value is less than 1 % which is contrary to para 4 of DPCO, 2013.

- IV. Thus by omitting the above said entry mentioned above, the ceiling price would be Rs. 2.42 per tablet.
- V. They further submitted that the working sheet of calculation of ceiling price of Amlodipine Tablets 5 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 Amlodipine Tablets 5 mg.

Comments of NPPA:

- (i) NPPA has fixed ceiling price Rs. 2.33/ tablet considering the Authority's decision as taken in 27th meeting held on 29.3.2016 (copy enclosed) which states that:-
 - (a) The lowest average PTR as worked out in accordance with the principles given below will be considered for determining the ceiling prices.
 - (b) PTR of all brands and generic versions of medicines with market share (MAT value) equal to or more than 1% (as per para 4 of DPCO, 2013).
 - (c) Even when same brands / generic versions of a medicine of a company have less than 1 % market share, the market share of all such versions of that medicine of that company is clubbed for the purpose of determining whether the company's market share is equal to or more than 1%. PTR of all such generic/branded versions are considered for working out average PTR.
 - (d) When same brands of medicines of a company are sold in different packs and when such packs have less than 1% market share, the market share of such different variants of that medicine of that company is clubbed for the purpose of determining whether the company's market share is equal to or more than 1% PTR of all such variants are also considered for working out the average PTR.
 - (e) Keeping in view of the consistency in fixing the ceiling price of scheduled formulations, Authority has decided to include the PTR of AMLIP 5mg tablet of M/s Cipla Limited.
- (ii) NPPA has fixed the ceiling price Rs. 3.06/tablet vide S.O. 1809(E) dated 21.6.2013 and the same was revised to Rs. 2.83, Rs. 3.01, Rs. 3.13 & Rs. 3.05/tablet vide S.O. 3773(E), 1156(E), 619(E) & 644(E) dated 20.12.2013, 28.4.2014, 26.02.2015 & 02.3.2016 respectively.
- (iii) As per information available with M&E division (through IPDMS report), the company is following ceiling price for subject formulation notified vide S.O.

1686(E) dated 09.5.2016 (copy enclosed). DOP is also requested to verify the same from the company.

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

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 9-5-2016 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 while calculating the PTR, NPPA has applied different yardsticks for different products. NPPA has furnished their Authority decision as follows :

“Even when same brands / generic versions of a medicine of a company have less than 1 % market share, the market share of all such versions of that medicine of that company is clubbed for the purpose of determining whether the company’s market share is equal to or more than 1%. PTR of all such generic/branded versions are considered for working out average PTR.”

This criteria has not been followed in case of Amlodipine tablets, even though the same has been followed in case of working sheet of Paracetamol tablet (Pacimol tablets) of different packs manufactured by M/s IPCA Laboratories Pvt. Ltd. It shows that there is a discrimination while calculating the PTR for different products.

NPPA clarification

NPPA has followed the decision taken in its 27th Authority meeting held on 29.3.2016, which is reproduced as below :-

“It was pointed out that the Authority in first meeting under DPCO, 2013 (held on 12.6.2013) had decided that the MAT value of the specific medicines manufactured by the same company in different brand names / generic names, may be clubbed for determining the market share (of more than or equal to 1%) for working out the ceiling prices of medicines included in Schedule-I. However, it is observed that when average PTR is worked out on the basis of the above principled decision taken at the first Authority meeting, in some cases, the average PTR and hence the ceiling work out to be higher than the figure worked out as per para 4 of DPCO, 2013; and lower in some cases. This was deliberated in detail, and it was decided that whenever application of the principle based on the decision of the first Authority Meeting works to the benefit of the consumers resulting in lower PTR and ceiling price, the ceiling price would be worked out accordingly.”

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 Para 18 read with Para 17 of DPCO, 2013, 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, it is stated that **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**, mentioned in amended list of scheduled 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 criteria for fixing ceiling price of the subject formulation, on examination, it is found that NPPA has erred in calculating ceiling price as per para 4 of DPCO, 2013, which reads 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:-

Step 1: *First the Average price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:-*

Average Price to Retail 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).”*

It clearly mentions the medicines which are to be taken for calculation. In the instant case, the principles applied by NPPA 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 10 formulations are to be considered having MAT value of more than 1% each instead of 21 considered by NPPA in its calculation. Accordingly, NPPA may be directed to refix the ceiling price in accordance with the provisions of DPCO by considering the PTR of 10 formulations only. The DPCO does not recognise a company for average PTR but only medicines / formulations.

5. Government Decision:

“The ceiling price fixation of Amlodipine Tablets by NPPA, vide S.O.No.1686(E), dated 09.05.2016, in deviation of DPCO, 2013, is hereby quashed and the NPPA is directed to refix the ceiling price in accordance with the provisions of DPCO by considering the PTR of the 10 formulations with more than 1% market share only. The DPCO does not recognise a company for average PTR but only medicines / formulations.”

Issued on this date, the 10th day of January, 2017.

(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**