

**No. 31015/7/2017-Pricing**  
**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 Modi-Mundi Pharma Pvt. Ltd. against price fixation of "N-acetylcysteine 200mg Sachet" vide NPPA order No. S.O. 4127(E), dated 22.12.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Review application dated 12.01.2017  
2) NPPA notification under review S.O. 4127(E), dated 22.12.2016  
3) Record Note of discussions held in the personal hearing held in the matter on 11.04.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Modi-Mundi Pharma Pvt. Ltd. (hereinafter called the petitioner) against notification S.O. No.4127(E), dated 22.12.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of N-acetylcysteine 200mg Sachet

2. The petitioner has contended as under:-

I. NPPA, vide notification being S.O 4127 (E) dated 22<sup>nd</sup> December, 2016 fixed the ceiling price of N - acetylcysteine 200 mg/gm (their formulation being Fluimucil 200 Mg. Granules 1 gm x 10 Sachet) at Rs. 6.99 per unit on the basis of an incorrect and false calculation in the draft / proposed calculation sheet which was circulated along with the Office Memorandum dated 06.12.2016. The said price fixation is incorrect and wrong for the following reasons:-

- (i) Out of the three formulations (namely Fluimucil 200 Mg. Granules 1 gm x 10 Sachet, Fluimucil (Elder) 200 Mg. Powder 3 Gm. and Fluimucil (Elder) 200 Mg. Granules 1 Gm.) mentioned in the calculation sheet (at Pg. No.5), Company is only manufacturing Fluimucil 200 Mg. Granules 1 gm x 10 Sachet and the other two formulations do not belong to Company as is wrongly and incorrectly mentioned in the calculation sheet.
- (ii) The two formulations (namely Fluimucil (Elder) 200 Mg. Powder 3 Gm. and Fluimucil (Elder) 200 Mg. Granules 1 Gm.) which are wrongly and incorrectly mentioned against their Company's name in the said working sheet were not available in the market (during the period of Aug, 2015 as mentioned in the proposed working sheet), thus their prices can-not be taken into account to fix the ceiling price of N - acetylcysteine 200 mg/gm sachet. It may please be noted that as per market sources the aforesaid two formulations are currently also not available in the market.

- (iii) In addition to the above, the correct PTR i.e. Rs. 84.67/- and MAT i.e. Rs.5.09 Lacs were also informed as against the PTR of Rs.84.30 and MAT of Rs.1,68,711 which is wrongly and incorrectly mentioned against the Company's name in the said working sheet.
- II. In the above regards, a representation was also sent on behalf of Company. Further, they have implemented the ceiling price as per ceiling price Notification S.O No. 4127 (E) dated 22<sup>nd</sup> December, 2016. Without prejudice to the above, It is pertinent to point that NPPA while fixing the ceiling price of N-acetylcysteine 200 mg/gm Sachet, has erroneously and inadvertently included and considered the price of N- acetylcysteine Injection 200 mg / ml (whose ceiling price has been arbitrarily reduced by 12.66% without any basis and without submitting the details of the 39<sup>th</sup> current meeting as mentioned in the said calculation sheet published on 06.12.2016 on NPPA's website) which has further negatively impacted the fixation of ceiling price of N- acetylcysteine 200 mg Sachet.
- III. They further submitted that ceiling price of every scheduled formulation is fixed/revised in accordance with provisions Para 4 of the DPCO, 2013 wherein, first, the Average price to retailer is calculated which is "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.)". The amount calculated herein above is then used to calculate the ceiling price as per the formula mentioned in the Step 2 of the Para 4 of the DPCO, 2013, but if certain formulations are not available in the market then the price of such formulations can-not be considered in terms of Para 4, therefore, fixing the ceiling price of N - acetylcysteine 200 mg/gm sachet on this basis is bad in law.
- IV. Due to the incorrect and inappropriate calculation as mentioned in the Calculation Sheet (as they wrongly and incorrectly included 2 formulations i.e. Fluimucil (Elder) 200 Mg. Powder 3 Gm. and Fluimucil (Elder) 200 Mg. Granules 1 Gm. which are not manufactured by the Company), the NPPA vide impugned notification wrongly and incorrectly fixed the ceiling price of N - acetylcysteine sachet 200 mg/gm Sachet from Rs. 8.43 per unit to Rs. 6.99 per unit.
- V. In view of above, Company requested that the notification being S.O. 4127(E) dated 22<sup>nd</sup> December, 2016 be withdrawn qua their formulation.

3. Comments of NPPA:

- (i) In this regard, it is mentioned that ceiling price of Rs. 6.99/gm for **N-acetylcysteine 200mg Sachet** was notified vide S.O. 4127(E) dated 22.12.2016 as per para 4, 6, 10, 11, 14, 16, 17 & 18 under DPCO 2013.
- (ii) The company stated that correct methodology was not followed in arriving at the ceiling price for **N-acetylcysteine 200mg Sachet**. The points raised by the company are not relevant. Price fixation has been done strictly in

accordance with the provisions of DPCO, 2013 and as per the decisions of 27<sup>th</sup> Authority meeting held on 29.3.2016. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	NPPA has considered the PTR and MAT value of Fluimucil 200mg Granules 10gm, Fluimucil (Elder) 200mg Powder 3gm & Fluimucil (Elder) 200mg Granules 1gm for calculating the ceiling price for <b>N-acetylcysteine 200mg Sachet</b> which is incorrect and wrong.	NPPA has considered the PTR and MAT value of Fluimucil 200mg Granules 10gm, Fluimucil (Elder) 200mg Powder 3gm & Fluimucil (Elder) 200mg Granules 1gm for calculating the ceiling price for <b>N-acetylcysteine 200mg Sachet</b> based on the data provided by the pharmatrac for the month of August 2015.
2.	Company has pointed out that 2 formulations namely Fluimucil (Elder) 200mg Powder 3gm & Fluimucil (Elder) 200mg Granules 1gm are wrongly and incorrectly mentioned against their company name. These products are not available in the market.	As per information available with Drug Today, Fluimucin 200mg/gm-3gm Sachet is available in pharmaceuticals market and M/s Elder Pharma has also not informed NPPA about the discontinuation of Fluimucin 200mg/gm-3gm Sachet & Fluimucin 200mg/gm-1gm Sachet as required under para 21(2) of DPCO, 2013.

4. During the personal hearing, the representatives of the company submitted that their company vide its letter dated 29.03.2017 also addressed a letter to Pharma Trac (who had provided the data) basis which the NPPA had fixed the ceiling price of N – accetylcysteine 200 mg sachet vide S.O. 4127 (E) dated 22.12.2016 interalia stating the data provided by their organization to NPPA basis which NPPA has fixed the ceiling price of N – accetylcysteine 200 mg sachet is incorrect and erroneous and requested them to rectify the same as this patent error by them had lead to incorrect fixation of prices. In response to the aforesaid letter, Pharma Trac vide its letter dated 07.04.2017 addressed to our company, substantiated the contention raised by our company and accepted the same (in any case the letter is self explanatory). The said letter has also been copied to NPPA as has been given to understand by Pharma Trac. In view of above, Company requested that the notification being S.O. 4127(E) dated 22<sup>nd</sup> December, 2016 be withdrawn qua their formulation.

#### 5. Examination:

The petitioner company has challenged the NPPA Order S.O. 4127(E), dated 22.12.2016 for price fixation of their formulation **N-acetylcysteine 200mg Sachet**. The main contention of the petitioner company is that two formulations namely Fluimucil (Elder) 200mg Powder 3gm and Fluimucil (Elder) 200mg Granules 1gm are wrongly and incorrectly mentioned against their company name. These products are not available in the market. NPPA stated that these formulations were taken for calculating

the ceiling price for N-acetylcyseine 200mg sachet based on the data provided by the pharmatrac for the month of August, 2015. However, the company approached the data providing company and got a letter in support of their claim. In view of this, NPPA may be directed to examine the documentary proof submitted by the company and re-fix the ceiling price of the formulation, on merit.

**5.2 NPPA, in the written submission, has stated that, if review petition is accepted, there will be a loss of approximately Rs.8176/- (approx) to the public.** In this connection, the mention of a notional loss figure by NPPA is unwarranted. Every review petition is examined and decided based on the interpretation of the provisions of DPCO, 2013 after following a quasi-judicial process. Mention of any notional loss figures without any objectively verifiable method is to argue a case on non-legal and non-DPCO basis, not relevant to judicial exercise of DPCO provisions, as the review petitions are decided in accordance with the provisions of DPCO, where extraneous considerations hold no merit.

**6. Government Decision:**

**“NPPA is hereby directed to examine the relevant documents/information furnished by the petitioner company and to re-fix the ceiling price of N-acetylcyseine 200mg Sachet on merit, within 30 days of this Order and send the compliance report to the Department.”**

Issued on this date, the 24<sup>th</sup> day of July, 2017.

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

To

1. M/s. Modi-Mundi Pharma Pvt. Ltd.  
1400, Modi Tower, 98, Nehru Place,  
New Delhi-110 019.
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