

**No. 31015/76/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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A wing, Shastri Bhavan  
New Delhi 110 001

**ORDER BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO,2013**

**Subject: Review application of M/s IPCA Laboratories against Price fixation of Methotrexate Tablets 2.5mg., 7.5mg and 10mg (Company's brand Folitrax) vide NPPA order S.O. No. 2193(E) dated 23/06/2016 issued under Drugs Prices Control Order, 2013 (DPCO 2013).**

**Ref: (1) Review application dated 18/07/2016**  
**(2) NPPA notification under review. S.O. No. 2193(E) dated 23/06/2016**  
**(3) Personal hearing held in the matter on 08.11.2016.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s IPCA Laboratories (hereinafter called the petitioner) against notification S.O. No. 2193(E) dated 23/06/2016 issued by National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Methotrexate Tablets 2.5mg., 7.5mg and 10mg (brand Folitrax).

2. The petitioner has contended that :-

- (a) NPPA has considered old and discontinued retail packs which appear in Pharmatrac.
- (b) NPPA has considered retail packs whose market share is less than 1% which is against laid down policy.
- (c) M/s Zydus Cadilla is shown as having multiple retail packs and these inaccuracies need to be verified. M/s Zydus Cadilla is marketing 4's pack only.
- (d) The accuracy of Pharmatrac is questionable and NPPA has unilaterally switched over to this source without consulting anybody in the industry and even ignoring what was laid down in the policy.

**3. Comments of NPPA:**

In this regard, NPPA stated that:-

- (i) NPPA has fixed the ceiling price of Rs. 4.26/tablet for **Methotrexate 2.5mg**, Rs. 10.32/tablet for **Methotrexate 7.5mg** & Rs. 10.81/tablet for **Methotrexate 10mg** vide S.O. 2193(E) dated 23.6.2016. The ceiling price of Rs. 11.27/tablet for **Methotrexate 7.5mg** was notified vide S.O. 1562(E) dated 14.6.2013 and the same was revised to Rs. 11.98, Rs. 12.44 & 12.10 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 the ceiling price of Rs. 13.95/tablet for **Methotrexate 10mg** was notified vide S.O. 1873(E) dated 26.6.2013 and the same was revised to Rs.

14.83, Rs. 15.40 & 14.98 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 and the same was revised to Rs. 10.32/tablet for **Methotrexate 7.5mg** & Rs. 10.81/tablet for **Methotrexate 10mg** vide S.O. 2193(E) dated 23.6.2016 under NLEM 2015.

- (ii) Shifting of outsource agency IMS to Pharmatrac & consideration of Pharmatrac data has been done correctly by NPPA as per para 9(2) of DPCO, 2013.

#### **4. Examination:**

**The representatives of the petitioner company did not attend the hearing. Hence, the proceedings were held ex-parte.**

The petitioner company in its review application contended that NPPA has considered old and discontinued retail packs which appear in Pharmatrac. M/s Zydus Cadila is shown multiple retail packs and these inaccuracies need to be verified since M/s Zydus Cadila is marketing 4's pack only. The petitioner company did not submit any documentary proof in support of its claim. Hence, the claim of the petitioner company cannot be accepted.

As per Para 4(i) of DPCO, 2013, 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 is to be considered while calculating the ceiling price of a scheduled formulation. It is perused from the calculation sheet that there are 8 products with SKU wise MAT of more than 1% market share, which should have been considered instead of Company wise MAT considered by NPPA. Therefore, NPPA may be directed to re-fix the ceiling price of formulation "Methotrexate Tablets 2.5 mg, 7.5 mg and 10 mg." considering only 8 formulations instead of 9 formulations considered by NPPA.

#### **6. Decision of the Government:**

**"NPPA is hereby directed to re-fix the ceiling price of "Methotrexate Tablets 2.5 mg, 7.5 mg and 10 mg." by considering only 8 formulations with SKU-wise MAT of more than 1% market share."**

Issued on this date, the 5<sup>th</sup> day of April, 2017.

**(Jai Priye Prakash)**  
**Secretary**

**For and on behalf of the President of India**

**To**

1. IPCA laboratories Ltd.  
125, Kandivli Industrial Estate,  
CTS No. 328, Kandivli (West),  
Mumbai 400067,

2. The Member Secretary  
National Pharmaceutical Pricing Authority  
YMCA Cultural Centre Building  
New Delhi – 110 001.

Copy to :

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. T.D., NIC for uploading the order on Department's Website