

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

A Wing, Shastri Bhawan,  
New Delhi 110 001

**CORRIGENDUM**

**Subject: Review application of M/s IPCA Laboratories Ltd. against price fixation of Methotrexate Tablets 2.5 mg, 7.5 mg and 10 mg (company's brand Folitrax) vide NPPA order No. S.O. 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 Ltd. (hereinafter called the petitioner) against notification S.O. No. 2193(E) dated 23.06.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Methotrexate Tablets 2.5 mg, 7.5 mg and 10 mg (brand Folitrax).

2. This review application was disposed of by the Department of Pharmaceuticals with the approval of competent authority vide Review Order of even number, dated 5<sup>th</sup> April, 2017 with the following decision :-

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

3. In this regard, it is noted that para 4 of DPCO, 2013 reads as under:-

**Step I.** 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.)

4. In view of para 3 above, it is clear that DPCO, 2013 recognises all the brands and generic versions of the medicines not SKU-wise data.

5. In view of the above, the part of the Government Decision, conveyed vide Para 6 of Order No. 31015/76/2016-PI.I, dated 05<sup>th</sup> April, 2017, is hereby substituted with following:-

**“NPPA is hereby directed to revise the ceiling price of Methotrexate Tablets 2.5 mg, 7.5 mg and 10mg, considering only the brands and generic versions of the medicine having market share more than or equal to 1% of the total Market turnover on the basis of MAT of that medicine.”**

This is issued with the approval of Competent Authority.

Issued on this, the 8<sup>th</sup> day of June, 2018.

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

**To**

- 1. M/s. 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-110001**

**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**