

**No. 31015/41/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhavan,
New Delhi 110 001

CORRIGENDUM

Subject: Review application of M/s Alkem Laboratories Ltd. against price fixation of “Uprise 60K IU Soft Gelatin Capsule (Cholicalciferol 60K IU), Cholicalciferol 1000 IU, Taxim O Forte Dry Syrup (Cefixime Oral Liquid 100 mg./5 ml and Cefixime Oral Liquid 50mg/5 ml” vide NPPA order No. S.O. 1687(E) dated 09.05.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 07.06.2016
2) NPPA notification under review S.O. No.1687(E) dated 09.05.2016
3) Record Note of discussions held in the personal hearing held in the matter on 25.07.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Alkem Laboratories Ltd. (hereinafter called the petitioner) against notification S.O. No.1687(E) dated 09.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Uprise 60K IU Soft Gelatin Capsule (Cholicalciferol 60K IU), Cholicalciferol 1000 IU, Taxim O Forte Dry Syrup (Cefixime Oral Liquid 100 mg./5 ml and Cefixime Oral Liquid 50mg/5 ml.

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 14th September, 2016 with the following decision :-

“NPPA shall re-fix and re-notify the price of the products of the petitioner company under Para 4, taking into account Para 9(5) of DPCO, 2013. Para 16(1) will not be applicable here.”

“NPPA is also directed to examine any relevant data furnished by the petitioner company on merits and to re-fix the ceiling price of their products under review within one month of the decision in this regard.”

3. The Schedule I of Drugs (Prices Control) Order, 2013 (DPCO, 2013) was revised vide Department of Pharmaceuticals had issued SO No.701(E), dated 10th March, 2015, in which certain new formulations were included in National List of Essential Medicines, 2015 (NLEM, 2015). As per provisions in para 9(5) of DPCO, 2013, the market based data to be considered for fixing the ceiling price of scheduled formulations, should be the data available for the month ending immediately before six months of the Notification.

4. The matter to factor the impact of Wholesale Price Index (WPI) for the year 2015 on those new formulations, which were included for the first time in the said Schedule, has been re-examined. Since the ceiling prices of all scheduled medicines as per provision of para 17(1) of DPCO, 2013 have not been fixed within sixty days from the date of Notification of revised Schedule I of DPCO, 2013 in March, 2016, and the market data of August, 2015 is being considered for fixing the ceiling price, the impact of WPI for the year 2015 would also be applicable.

5. In view of the above, first part of the Government Decision, conveyed vide Para 5 of Order No.31015/41/2016-PI.I, dated 14th September, 2016, is hereby substituted with following:-

“The grievance of the company, that WPI impact should not be applicable while fixing the ceiling price of those formulations included for the first time in NLEM, 2015, cannot be accepted. In the instant case, the market data considered, as per para 9(5) of DPCO, 2013, was the data of August, 2015. Therefore, the applicability of the impact of WPI for the year 2015 is considered to be in order.”

This is issued with the approval of Competent Authority.

Issued on this, the 27th day of November, 2017.

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

To

- 1. M/s. Alkem Laboratories Ltd.
Alkem House, Senapati Bapat Marg,
Lower Parel, Mumbai-400 013.**
- 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**