

**No. 31015/7/2013-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhawan,  
New Delhi 110 001

**CORRIGENDUM**

1. A review application, dated 08.03.2016 was filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Sun Pharmaceutical Industries Limited (hereinafter called the applicant) against notification S.O. No. 579(E) dated 24/02/2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of "Histac EVT 2's AI Strip and Fucibet Cream 15 gm AI Tube" based on review order No. 31015/7/2013-PI.I dated 07/10/2015.

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 21<sup>st</sup> June, 2017 with the following decision :-

**"The grievance of the petitioner company in respect of Histac EVT 2's AI strip has no merit and deserves to be rejected.**

**However, in case of Fucibet cream 15 mg AI tube, as it was not included either in NLEM 2011 or NLEM 2015, the provisions applicable for non-scheduled formulations as per DPCO needs to be applied. Therefore, NPPA is directed to fix the price of Fucibet cream 15 mg AI tube as per provisions applicable for non-scheduled formulations in DPCO, 2013, within 30 days from the date of issue of this order."**

3. The review order no. 31015/7/2013-PI.I dated 21/06/2017 has been re-examined based on the suggestion received from National Pharmaceutical Pricing Authority (NPPA) vide their letter No. 20(172)/2017/DP/NPPA/Vol-II dated 01/01/2018.

4. There is no provision in DPCO, 2013 for fixation of any retail/ceiling price for non-scheduled formulations. As per para 20 of the Drugs (Prices Control) Order, 2013 (DPCO, 2013), the provision is to monitor the maximum retail prices (MRPs) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten per cent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months.

5. Fucibet cream 15 mg AI tube was neither included in original schedule-I of DPCO, 2013, (i.e. National List of Essential Medicines, 2011) nor in revised schedule-I (i.e. NLEM, 2015). Therefore, the said product is a non-scheduled formulation and not covered under price control.

6. In view of para 5 above, the part of the Government Decision, conveyed vide Para 5 of Order No. 31015/7/2013-Pl.I, dated 21<sup>st</sup> June, 2017, is hereby substituted with following:-

**“The grievance of the petitioner company in respect of Histac EVT 2’s AI strip has no merit and deserves to be rejected.**

**However, Fucibet cream 15 mg AI tube was neither included in original schedule-I of DPCO, 2013, i.e. National List of Essential Medicines, 2011 nor in revised schedule-I (i.e. NLEM, 2015). Therefore, the said product is a non-scheduled formulation and not covered under price control.”**

This is issued with the approval of Competent Authority.

Issued on this, the 18<sup>th</sup> day of May, 2018.

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

**Copy to:**

- 1. Sun Pharmaceuticals Industries Ltd., 8-C, 8<sup>th</sup> Floor, Hansalya Building, 15- Barakhamba Road, Connaught Place, New Delhi – 110001**
- 2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001**
- 3. PS to Hon’ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
- 4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.**
- 5. PSO to Secretary (Pharma)**
- 6. T.D., NIC for uploading the order on Department’s Website**