

**No. 31015/91/2016-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 Sun Pharmaceutical Industries Limited against Price fixation of Nitrofurantoin 100 mg capsule vide NPPA order no. S.O. 3180(E) dated 07/10/2016 issued under Drugs Prices Control Order, 2013 (DPCO 2013)**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Limited (hereinafter called the petitioner) against notification S.O. No. 3180(E) dated 07/10/2016 issued by National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Nitrofurantoin 100 mg capsule.

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 6<sup>th</sup> March, 2017 with the following decision:-

**NPPA is hereby directed to 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, and without applying WPI change in ascertaining the ceiling price. The same principles should be applied to all other such cases also by NPPA.**

**NPPA is further directed to exclude the product pack of U FREE 100mg capsule 14x10 of M/s Zydus Cadilla in the price calculation of Nitrofurantoin 100 mg, verify the data of URIFIST CP100 MG CAPSULE OF M/S Cipla and to re-fix the ceiling price of Nitrofurantoin 100mg capsule, on merit.**

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 10<sup>th</sup> 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, the Government Decision, conveyed vide Para 4 of Order No.31015/91/2016-PI.I, dated 6<sup>th</sup> March, 2017, 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.”**

**“NPPA is further directed to exclude the product pack of U FREE 100mg capsule 14x10 of M/s Zydus Cadilla in the price calculation of Nitrofurantoin 100 mg, verify the data of URIFIST CP100 MG CAPSULE OF M/S Cipla and to re-fix the ceiling price of Nitrofurantoin 100mg capsule, after hearing the petitioner.”**

This is issued with the approval of Competent Authority.

Issued on this date, the 22<sup>nd</sup> day of January, 2018.

**(Jai Priye Prakash)**  
**Secretary**  
**For and on behalf of the President of India**

**To**

1. Sun Pharmaceutical Industries Ltd  
8-C, 8<sup>th</sup> Floor, Hansalya Building,  
15, Barakhamba Road, Conaught Place,  
New Delhi-110001
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 Bhavan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhavan, New Delhi for information.
3. T.D. NIC for uploading the order on Department's website.