

**No. 31015/58/2017-Pricing
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 Glenmark Pharmaceuticals Limited against price fixation of "Clotrimazole 1% cream" vide NPPA order No. S.O. 1271(E), dated 21.04.2017 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 Glenmark Pharmaceuticals Limited (hereinafter called the petitioner) against notification S.O. No.1271(E), dated 21.04.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Clotrimazole 1% cream.

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 24th July, 2017 with the following decision:-

"NPPA is hereby directed to examine the documentary proof submitted by the petitioner company about the market share of M/s Midas having more than 1%, and after confirming the data of the said company from Pharmatrac, revise/refix the ceiling price of Clotrimazole 1% Cream, on merit."

"NPPA is further directed to re-fix and re-notify the price of the product of the petitioner company under para 4, without applying WPI change in ascertaining the ceiling price. The same principle should be applied to all other such similar cases also by NPPA".

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, the Government Decision, conveyed vide Para 6 of Order No.31015/58/2017-Pricing, dated 24th July, 2017, is hereby substituted with following:-

“NPPA is hereby directed to examine the documentary proof submitted by the petitioner company about the market share of M/s Midas having more than 1%, and after confirming the data of the said company from Pharmatrac, revise/refix the ceiling price of Clotrimazole 1% Cream, on merit.”

“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 date, the 10th day of January, 2018.

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

To

1. M/s Glenmark Pharmaceuticals Limited,
7-D, Atmaram House, Tolstoy Marg,
NEW DELHI-110001.
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