

No. 31015/28/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: Review application of M/s Bayer Zydus Pharma Pvt. Ltd. against price fixation of Clotrimazole Cream 1% 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 18.05.2016
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 21.6.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Bayer Zydus Pharma Pvt. 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 Clotrimazole Cream 1%.

2. The petitioner has contended as under:

- (1) While fixing the ceiling price of "Clotrimazole Cream 1 % under para 4 of the DPCO, 2013, the NPPA has taken into consideration **wrong pack description of CANESTEN 1% OINMENT 10 GM instead of CANESTEN CREAM 15 gm.**
- (2) **They said that CANESTEN 1% OINMENT 10 GM is Clotrimazole + Beclomethasone where as CANESTEN CREAM 15 gm is Clotrimazole cream 1%.**
- (3) They further submitted that PTR and internal sales value as of MAT- August, 2015, for the Product CANESTEN 15 GM (Clotrimazole cream 1%.):
 - (i) PTR (Price to retailer) for CANESTEN 15 GM is Rs. 43.60/-
 - (ii) Internal MAT (Moving annual Trend) for CANESTEN 15 GM is Rs. 39,837,011/-.

They requested for a revised calculation based on para 4 of the DPCO, 2013.

3. The contentions of petitioner and the NPPA were heard on 21st June, 2016. During the hearing, the petitioner company did not submit any more submission. NPPA representative requested the hearing authority to direct the company to submit the documents / information as per OM F.No.19(714)/2016/Div.II/DP/NPPA, dated 20th May,

2016, which states that ***“all the companies aggrieved by NPPA’s price fixation may make representations, if any, against the ceiling prices fixed by the NPPA, by submitting documents / information of Price to Retailer (PTR) and Moving Annual Turnover (MAT) data along with supporting documents like copies of invoices to retailer and samples of August, 2015 duly self-attested with name, designation, mobile no., signature & seal of the authorised officer of the company, within 15 days of the price notification in order to enable NPPA to take necessary action in this regard.”*** The company representative submitted the copy of the letter containing relevant documents / information with data to NPPA representative as required under the abovementioned OM of NPPA dated 20th May, 2016 in the meeting.

The NPPA representative stated that the same will be examined by NPPA and may be put up in the Authority Meeting of the NPPA.

4. **Decision of the Government:**

NPPA is directed to re-fix the ceiling price of “Clotrimazole Cream 1%” after taking into consideration data furnished by the petitioner company on merit within a period of one month from the date of issue of this Order.

Issued on this date, the 22nd day of July, 2016.

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

To

1. M/s. Bayer Zydus Pharma Pvt. Ltd.
Bayer House, Central Avenue,
Hiranandani Estate, Thane (West)-400607.
Maharashtra.
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