

No. 31015/31/2016-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 Glenmark Pharmaceuticals Ltd. against price fixation of "Clotrimazole 1% Cream" 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 16.6.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Glenmark Pharmaceuticals 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 1% Cream"

2. The petitioner has contended as under:

(i) Full due diligence had not been done to capture data of all brands to calculate the Ceiling prices. List of formulations that should have been considered in the first place and have been totally missed in the working sheet while arriving at the ceiling price of Clotrimazole 1% Cream.

Pack Description	Company	Pack size	PTR /Pack	Market Share*
CANESTEN CREAM 1 % 15 G	BAYER ZYDUS PHARMA	15 Gm	43.69	18.08%
CLEAN & DRY CREAM 1 % 15 G	MIDAS CARE	15 Gm	46.83	5.68%
CANDID GOLD CREAM 1 % 30 G	GLENMARK PHARMA	30 Gm	83.13	2.61%

(ii) Data of this particular brand has erroneously found its way in the database used by NPPA and the working sheet should not have included the date in respect of the Canitross brand unless evidence to the contrary is put before the Authority.

Pack Description	Company	Pack size	PTR / Pack
CANITROSS CREAM 30 GM	ALBATROSS HEALTH CARE PVT LTD	30 Gm	29.71
CANITROSS CREAM 50 GM	ALBATROSS HEALTH CARE PVT LTD	50 Gm	53.33

They requested to take the necessary steps as deemed appropriate and assist in re-fixing of revised Ceiling Price in respect of Clotrimazole 1 % cream.

3. NPPA submitted that :

- I. NPPA has fixed the ceiling price for above mentioned pack based on the data submitted by Pharmatrac as per existing practices and fixed the ceiling price under para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013.
- II. Representation submitted by M/s Glenmark / companies based on OM F. NO. 19(714)/2016/NPPA Div.II dated 20.05.2016 (uploaded on NPPA's website) is under examination.
- III. Necessary action in this regard will be taken by this office after examination and analysis of the data received from the companies and approval of the Authority.

4. The contentions of petitioner and the NPPA were heard on 16th June, 2016. In the hearing, the company submitted that Ceiling price calculation of Clotrimazole 1% CREAM is inaccurate and incomplete as full data has not been considered while arriving at the price. Specifically, the below mentioned formulations, that should have been considered in the first place have been totally missed in the working sheet. The company procured and handed over physical pack/carton of some of them during the hearing.

Pack Description	Company	Pack size	PTR / Pack	Market Share*
CANESTEN CREAM 1 % 15 G	BAYER ZYDUS PHARMA	15 Gm	47.53	18.08%
CLEAN & DRY CREAM 1 % 15 G	MIDAS CARE	15 Gm	57.73	5.68%
CANDID GOLD CREAM 1 % 30 G	GLENMARK PHARMA	30 Gm	83.13	2.61%

*As per ORG IMS Aug'15

- The company's contention is that data of *Canitross* brand (Albatross Healthcare Pvt Ltd) has erroneously found its way in the database used by NPPA. The company has been unable to trace any physical pack of the same and the data thus should not have included *Canitross* brand unless evidence to the contrary was put before the Authority.

Pack Description	Company	Pack size	PTR / Pack
CANITROSS CREAM 30 GM	ALBATROSS HEALTH CARE PVT LTD	30 Gm	29.71
CANITROSS CREAM 50 GM	ALBATROSS HEALTH CARE PVT LTD	50 Gm	53.33

Company requested to consider the above points and help re-fixing the correct price of Clotrimazole 1% cream at the soonest.

5. The NPPA representative stated that the information submitted by the Company will be examined and may be put up in the Authority Meeting of NPPA.

6. **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 of 08th of July, 2016.

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

To

1. M/s. Glenmark Pharmaceuticals Ltd.
7-D, Atmaram House, 1, Tolstoy Marg,
New Delhi-110 001.
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**