

**No. 31015/58/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

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**A- Wing, Shastri Bhawan,
New Delhi 110 001**

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).

Ref:

- 1) Review application dated 17.05.2017
- 2) NPPA notification under review S.O. 1271(E), dated 21.04.2017
- 3) Record Note of discussions held in the personal hearing held in the matter on 27.06.2017.

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. The petitioner has contended as under:-

(i) Company has submitted that Albatross Healthcare Pvt Ltd products do not have a market share of 1 %. However the data of this company has been once again included in the working sheet to calculate the revised Ceiling price. They also attached the annual report and financial statement procured from Ministry of Corporate Affairs with respect to the said Company.

Appeal:

They believed that the supporting documents provided by them would convince Department that the market share of the Albatross Healthcare Pvt. Ltd is far lower than 1% market share and has been wrongly considered for calculation by NPPA in the working sheet. So the same may be deleted and subsequently the calculation, re-worked.

(ii) They had pointed a discrepancy in data with regard to M/s MIDAS Care. Though NPPA seem to have relooked at the data of the said company, as per company's analysis, the market share of product mentioned in the working sheet is still not accurate.

Same may be cross verified with Pharmatrac data. For further information please refer to the table below.

Pack Description	Company	Pack size	PTR / Pack	Market Share*
CLEAN & DRY CREAM 1 % 15 G	MIDAS CARE	15 Gm	59.52	5.07%

*Arrived after considering Sales Value as per ORG IMS Aug'15 is Rs. 1,58,56,710

Appeal: It is urged that the data mentioned in the table above may be verified and rectified.

- (iii) The ceiling price of Clotrimazole 1% was declared for the very first time on 09.05.2016. In this case, there was no ceiling price of the product on 1.4.2016. So, when there existed no ceiling price as on 1.4.2016, there could not be a revision of ceiling price due to WPI effective from 01.04.2016. The same position was articulated in the order dated 06/10/2016 in the review matter of M/s Alkem Laboratories Limited.

Appeal: NPPA should rework the calculation by deleting the wrongfully considered Negative WPI impact in their working sheet.

Final Prayer:

By company's calculation, Company submitted that NPPA still has not considered the rightful, updated data which when considered should bring the Ceiling Price to approximately Rs. 3.04/gram and not what has been notified by NPPA.

3. Comments of NPPA:

- I. The ceiling price of Rs. 2.49/gm for **Clotrimazole 1% Cream** was notified vide S.O. 1271(E) dated 21.4.2017 and the same was revised to Rs. 2.57/gm for **Clotrimazole 1% Cream** vide S.O. 1871(E) dated 09.6.2017 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.
- II. The company has stated that correct methodology was not followed in arriving at the ceiling price for **Clotrimazole 1% Cream**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	The data of M/s Albatross Healthcare Pvt. Ltd. is not to be considered for fixing the ceiling price as the market share of M/s Albatross Healthcare Pvt. Ltd. was found less than 1%.	NPPA has notified ceiling price Rs. 2.57/gm for Clotrimazole 1% Cream vide S.O. 1871(E) dated 09.6.2017. <u>The calculation sheet shows that the product of M/s Albatross Healthcare Pvt. was not considered since it has market share of less than 1%.</u>

2.	The data of M/s Midas Care was also not considered on the same ground.	<u>The data of M/s Midas Care was also not considered for fixing the ceiling price as the market share of M/s Midas Care was found to be less than 1%.</u>
3.	Company challenged the implementation of WPI while calculating the ceiling price, as subject formulation was included in NLEM 2015 for the first time.	The policy of application of WPI of 2016 over 2015 in determination of ceiling price of scheduled formulations under NLEM 2015 (revised Scheduled-I of DPCO, 2013) has been consistently applied by NPPA as per the decision taken in 27 th Authority meeting held on 29.3.2016; as the base data taken for consideration is August 2015. Accordingly WPI of 2016 over 2015 is added to the computation. When the price is revised in 2017, the WPI of 2017 over 2016 has been added to the computation.
		Detail of trade margin based on AIOCD-AWACS data as on August 2015:- Trade Margin from PTS Rs. 38.88% (22.26/57.26*100)

III. The company has not challenged any notification in respect of **Clotrimazole 1% Cream** in the Court.

4. During the personal hearing, the representatives of the company made the following submissions in addition to the written submission already submitted –

Even though the ceiling price vide the above SO is notified upwards, the company would give effect to the same only from the next batch thus benefitting the patients only. This being a pre-requisite for an applicant to come into review, to that end, the compliance to the same may be considered done.

In the review application, the Company raised couple of contentions and sought relief which are as follows:

- 1) The brand of Albatross Healthcare Pvt Ltd does not have a market share of 1% and NPPA has wrongly considered that data. The same has been addressed already by NPPA while notifying the price on 9 June 2017 vide SO 1871(E). So the company is dropping this ground from this review as on date.
- 2) As regards a discrepancy in data with regard to M/s MIDAS Care, though NPPA seems to have relooked at the data of the said company, as per company's analysis, the market share of product mentioned in the working sheet is still not accurate as per the working sheet dated 9.06.2017 uploaded along with the SO 1871(E).

The company also cross verified with Pharmatrac on the data of M/s MIDAS Care product Clean & Dry Cream 1% 15Gm and found that their contention is correct and the market share of M/s MIDAS Care is more than 1% as on August 2015. The company submitted the letter of Pharmatrac to corroborate their argument that NPPA should include the data of M/s MIDAS Care in calculation of the ceiling price. Details of the said product are captured in the table below for ready reference.

Pack Description	Company	Pack size	PTR / Pack Aug'2015	MAT (in Crs)Aug' 2015	MAT Aug15 MS %
CLEAN & DRY CREAM 1% 15G	MIDAS CARE	15 Gm	59.52	1.61*	5.94

*As per pharmatrac data Aug 2015

- The ceiling price of Clotrimazole 1% was declared for the very first time itself on 09.05.2016. Thus, no ceiling price of the product existed on 1.4.2016. So, when there existed no ceiling price as on 1.4.2016, there could not be a revision of ceiling price due to WPI effective from 1.04.2016. The same position was articulated in the order dated 06/10/2016 in the review matter of M/s Alkem Laboratories Limited (Ref: 31015/43/2016-PI.I). In light of the above, the NPPA should not have considered the negative WPI while calculating the Ceiling price.

In wake of the foregoing, the company representative requested to direct NPPA to re-fix the Ceiling price of Clotrimazole 1% cream at the earliest.

NPPA representative submitted that the matter may be examined on submission of requisite documents by the company.

5. Examination:

As regards the issue of market share of M/s Albatross Healthcare Pvt. Ltd., it is seen from the calculation sheet that the two products, viz. Canitross 1% cream 25gm and Canitross 1% 50gm, of the said company are having SKU-wise market share of less than 1% and NPPA has not considered both these products for averaging purposes. Therefore, the grievance of the petitioner company has got no merit on this issue. In the case of M/s Midas, the petitioner company has submitted documentary proof that the brand Clean & Dry Cream, (containing Clotrimazole) of M/s Midas is having market share of 5.94%. Incidentally, the ceiling price of the subject formulation was upwardly revised (from Rs.2.49/gm to Rs.2.57/gm) vide SO 1871(E), dated 9.6.2017 in compliance of directions of Delhi High Court against the WP filed by M/s Reckitt Benckiser Healthcare India Pvt. Ltd. However, as seen from the calculation sheet with the said OM, the market share of Midas is shown only 0.04%. NPPA may be 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 other contention of the company is that the application of WPI while fixing the ceiling price of the formulation **Clotrimazole 1% Cream** is not in accordance with the provisions of DPCO, 2013. In this regard, it is submitted that para 16(1) of DPCO, 2013 reads as under:

“The Government shall revise the ceiling prices of scheduled formulations as per the annual Wholesale Price Index (WPI) for preceding year on or before 1st April of every year and notify the same on the 1st day of April every year”

It is seen that applicability of Para 16 is appropriate **only in the cases where there is revision of prices**. Since it is a case of **fixation of price** of a formulation that has become scheduled for the first time, the concept of **applicability of WPI does not seem to be correct**.

In this case, **there is no ceiling price of the product as on 1.4.2016. Ceiling price is fixed for the first time on 21.04.2017**. Therefore, in the instant case, there is no revision of ceiling price due to WPI. **Applying WPI, whether negative or positive, without having the ceiling price, is not in accordance with the provisions of DPCO**. Hence, NPPA has erred in applying WPI in this case, where it is not applicable.

In view of the above, NPPA may be 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**.

6. **Government 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”.

Issued on this date, the 24th day of July, 2017.

(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