

No.31015/61/2023-Pricing (E-23872)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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Room No. 340-B, A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s Glenmark Pharmaceuticals Limited (hereinafter called the “Applicant”) filed a Review Application dated 27.04.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 1577(E) dated 31.03.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Clotrimazole cream 1%.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 14.09.2023 and presented their respective logics.

3. Major contentions raised by the Applicant:

It was contended, on behalf of the Applicant, that NPPA has erred in determining the ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 The Applicant had submitted a representation to NPPA in pursuance to its OM 12(90)/2022/DP/NPPA/Div-II dated 25th November, 2022 regarding submission of representation against any draft calculation of ceiling price with certain information/documents within a period of 10 working days from the date uploading of the draft working sheet on the NPPA website. The Applicant in its representation to NPPA pointed out certain anomalies in the data considered in calculating the ceiling price of Clotrimazole Cream 1% along with available supporting documents like pack shots indicating the correct price. Despite this, NPPA notified the ceiling price of Clotrimazole Cream 1% vide S.O. No. 1577(E) dated 31.03.2023 without considering the correct PTR as shown in Table below:

Product Name	Company	PTR as per NPPA working sheet	Actual MRP	Actual PTR to be considered in the working sheet by NPPA
Surfaz 1 % Cream 15 gm	Franco	32.29	50.00	35.71
Imidil Skin 1% Cream 15 gm	Hetero	25.11	38.75	27.68

3.2 Further, NPPA did not consider some products having market share of more than 1% for calculating the ceiling price of the subject formulation. These products are mentioned in the table below:

Product Name	Company Name	Pack Size	Actual PTR of in Jul'22 as Per Pharmatrac	Market Share MAT% as per Pharmatrac
New Itch Guard 1 % Cream 15 gm	Reckitt Benckiser	15 gm	63.02	5.5%
Clean and Dry 1 % Cream 15 gm	Midas Care	15 gm	88.54	4.3%

3.3 Thus, NPPA has considered the incorrect data for calculating the ceiling price of the subject formulation even though the Applicant submitted the correct data to NPPA.

4. Gist of clarifications made by NPPA:

NPPA on the other side argued that the instant review regarding 'Clotrimazole Cream 1%' is not tenable on the following grounds:

4.1 As per the provisions of DPCO [Para 16(2)], the manufacturers may increase the MRP of scheduled formulations once in a year, in the month of April on the basis of WPI. Further, as per para 16(3), information about the revision, if carried out, shall be forwarded to the Government in Form-II within a period of 15 days of such revision. This implies that Form-II for price revision based on WPI may be submitted latest by 15th May. Revisions are carried out by NPPA in the PTR in case the representations are received within 10 working days of uploading of working sheets and Form-II/Form-V have been filed on or before 15th May in IPDMS in respect of the PTR of companies mentioned in such representation.

4.2 Accordingly, the claims made in the representations received from the Applicant was cross verified by NPPA from the Form-II/Form-V submitted by the companies mentioned in the representation. In the instant case, the Applicant has represented that the PTR of two companies viz. M/s Hetero and M/s Franco-Indian Pharmaceuticals Pvt. Ltd. is higher than Pharmarack data used in calculation of the ceiling price. NPPA confirmed that M/s Hetero did not file either From-II or Form-V, while M/s Franco-Indian Pharmaceuticals Pvt. Ltd. filed Form-V on 22.06.2022 i.e. after 15.05.2022 but did not file Form-II. Hence price revision has not been considered.

4.3 In case of the brand “New Itch Guard 1% Cream 15 gm” of M/s Reckitt Benckiser, Pharmatrac have confirmed that the product contained “BENZYL ALCOHOL + TERBINAFINE” not “CLOTRIMAZOLE”. Hence, the same was not considered for ceiling price calculation of the above mentioned formulation. Further, in case of the brand “Clean and Dry Cream 15 gm” of M/s Midas Care, is as per web sources, the composition is Clotrimazole 2% cream base selling at MRP of Rs. 119. Hence the same was not considered for ceiling price calculation of the above mentioned formulation.

5. Examination:

5.1 In fixing the ceiling price of Scheduled formulations, NPPA has followed the due provisions of DPCO. Thus, NPPA has taken due cognizance of the provisions under Para 16(2) and 16 (3) of DPCO which provides that manufacturers may avail the increase in MRP of scheduled formulations once in a year, in the month of April, on the basis of the WPI; and, that such information about the revision, if carried out, shall be forwarded to the Government on IPDMS in Form-II and Form V within a period of fifteen days. DPCO also expressly maintains that non-submission of information under Para 16 (3) shall be construed as non-revision of MRP. NPPA has taken the relevant prices following these provisions of DPCO.

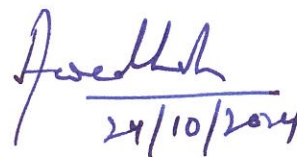
5.2 Further, composition of the brands of "New Itch Guard 1% Cream 15 gm" of M/s Reckitt Benckiser, and "Clean and Dry Cream 15 gm" of M/s Midas Care is not Clotrimazole 1% and hence, NPPA did not consider these for Ceiling price calculation of the subject formulation.

5.3 Therefore, in view of the facts as at paras 5.1 and 5.2 above, arguments and logics given by NPPA are accepted.

6. Decision:

The action of NPPA fixing the ceiling prices of Clotrimazole Cream 1% vide SO no. 1577(E) dated 31.03.2023 is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 24th day of October, 2024.



(Awadhesh Kumar Choudhary)

Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

To:

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Copy to:

1. Chairperson, NPPA, New Delhi
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi
3. Technical Director, NIC for uploading the order on DoP's Website.
4. Guard File

