

No.31015/18/2019-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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

Order

1. This is an order disposing of a review application dated 06.12.2019, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Skymap Pharmaceuticals Limited (hereinafter called the applicant) against notification S.O. No.4103(E), dated 14.11.2019 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail prices of Fluconazole Tablets 300mg.

2. The main contentions of the applicant are as given below :

(i) Company had submitted form-1 application for the Retail Price approval of Fluconazole tablets 300 mg to NPPA on 21/09/2019. The NPPA notified the retail price approval as Rs. 16.16/ Tab vide S.O. 4103(E) dated 14/11/2019.

(ii) Earlier NPPA's authority fixed the ceiling price of Fluconazole 200 mg tablet at Rs. 18.38/ tab and Fluconazole 400 mg tablet at Rs. 30.57/ tab based on the WPI increased 4.2662% vide 1485(E) dated 29/03/2019.

(iii) For the computation of Retail price for Fluconazole 300 mg tablet, NPPA used the PTR of the product of M/s Systopic Laboratories Ltd. as per Pharma Trac data and the draft working sheet was uploaded on NPPA website on 18/10/2019. NPPA used the Pharma Trac data of a 'Without Price Approval (WPA)' case to approve the Retail Price.

(iv) In view of the above, the company requested DoP to review its form- I application by considering ceiling price of Fluconazole 200 mg & 400 mg tablet which are approved by NPPA, because how the retail price of Fluconazole 300 mg tablet can be less than Fluconazole 200 mg tablet.

3. Comments of NPPA:

(i) The NPPA's authority fixed the Retail Price of Fluconazole 300 mg at Rs. 16.16 per tablet excluding GST in accordance with Para 5 of DPCO, 2013. The company's contention that the NPPA used the Pharmatrac data of a "Without Price Approval (WPA)" to approve the Retail Price of their Form-I application, **has no merit**. On examination of the Pharmatrac data, it was found that M/s Systopic Laboratory Ltd launched AF 300 mg in Jan 2003 when DPCO, 2013 was not in force. Therefore, AF 300 mg tablet doesn't come under the purview of WPA clause.

(ii) The contention raised by the company that the retail price of Fluconazole 300 mg tablet cannot be less than Fluconazole 200 mg tablet, it may be stated that similar aberration has also been noted while fixing prices of some other formulations i.e. higher strength of a formulation has lower price than its lower strength. However, as per the

existing mandate, NPPA fixes the retail price based on market based methodology as per para 5 of DPCO, 2013 and NPPA has strictly followed the provisions of the DPCO, 2013. In view of the above, the contention of the company **has no merit**.

(iii) The company did not make any representation against uploading of the worksheet prior to its notification.

4. Examination:

4.1 Before notifying the retail price of Fluconazole Tablets 300mg vide SO 4103(E), dated 14th November, 2019, the NPPA displayed the draft calculation sheet on its website on 18.10.2019, giving ample opportunity to the company to file its objection, if any. However, the company did not make any representation against the draft worksheet uploaded on the website by the NPPA.

4.2 As per existing provisions in para 5 of DPCO, the retail price of new drug is fixed by considering the PTR of the similar formulation available in domestic market. The NPPA fixed the retail price of Fluconazole Tablet 300mg by considering the PTR of formulation with brand name 'AF' of 300mg strength being manufactured by M/s Systopic Laboratories Ltd. as per the provisions of DPCO. Therefore, the objection raised by the company that the price fixed for 300mg is less than the retail price of 200mg has got no merit, as the retail price is fixed strictly as per provisions in the DPCO.

4.3 As regards the contention of the company that the NPPA has used the Pharmatrac data of a "Without Price Approval (WPA)" case to fix the retail price of its product, the NPPA clarified that the product AF 300mg, (the PTR of which was considered while fixing the retail price) was launched by M/s Systopic Laboratory Ltd. in January, 2003 when DPCO 2013 was not in force. Hence, the AF 300 mg tablet is not a WPA case and, therefore, the contention of the applicant does not have merit.

4.4 In view of the above, the present review application is not sustainable and needs to be rejected.

5. Decision:

The retail price of Fluconazole Tablets 300mg was fixed vide SO 4103(E), dated 14.11.2019 by strictly following the provisions in para 5 of DPCO. Hence, the present review application is not sustainable and stands rejected.

Issued on this, the 16th day of June, 2020.

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

Copy to :-

1. M/s Skymap Pharmaceuticals Limited, 302, Narmada Block-5, Pocket D-6, Vasant Kunj, New Delhi-110070.
2. Chairperson, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001.
3. PS to Hon'ble Minister(C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary(Pharma), Shastri Bhawan, New Delhi for information.
6. Joint Secretary(Pharma), Shastri Bhawan, New Delhi for information.
7. T.D., NIC for uploading the order on Department's Website.