

No. 31015/42/2018-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 10.09.2018 filed by M/s KonTest Chemicals Limited (hereinafter called the applicant) under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against notification S.O. No.3982(E), dated 13.08.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail price of Dicyclomine HCL 20mg tablet.

2. The applicant contented that the retail price fixed is not commercially viable to the company, as the price of Dicyclomine HCL APIs is nearly 100% more compared to its price prevalent 3 years ago. Company further stated that as per paragraph 6(1)(b), to calculate the average price of schedule drugs, there should have been minimum five manufacturers for any formulation. Dicyclomine 10mg is a schedule drug, therefore, Dicyclomine 20mg tablet comes under the category of new drug. NPPA has considered only one manufacturer from the market.

2.2 The applicant also stated that they are marketing their products in West Bengal, Orissa, NER, Bihar, Jharkhand and UP, and the product COLIGON, which NPPA considered for the price fixation, is not available in the market. The applicant submitted that said manufacturer is not promoting/manufacturing that product since it is not commercially viable. The applicant further submitted that NPPA has issued several notices to all manufacturers to obtain the data to fix the price of Schedule formulation of Dicyclomine HCL 10 mg, tablet. Since there was no manufacturer, NPPA could not obtain the data and finally NPPA fixed the price as per the data available with them which is not relevant as per the Paragraph 4(1) of DPCO, as amended. In such case, the price which NPPA has fixed for the company's product is not commercially viable to the company.

2.3 The applicant further stated that the said molecule is included as scheduled drug in National List of Essential Medicines (NLEM). Hence, the said molecule product is very much important to the general public. The said molecule Dicyclomine HCL is the best among others in Antispasmodic segment drugs and can be made available in affordable price compared to other drugs' price. The respective authorities should ensure for availability of such medicines. However, no manufacturer will show interest to market any products which are not commercially viable to them, ultimately, it impacts on general public about the availability of drugs with affordable price. The applicant requested to review the price order and revise the price not less than Rs.2.00 per tablet plus taxes.

3. NPPA's Comments:

3.1 NPPA stated that as per the provisions of DPCO, market based pricing exercise is followed. There is no provision of cost based price exercise in DPCO. The issue raised by the company has no merit as the price of the subject formulation is retail price specific to the petitioner company.

3.2 NPPA has notified the retail price of the subject formulation considering the data submitted by the Pharmatrac for the period of November 2017. Para6(1)(b) of DPCO states that wherever there is less than 5 manufacturers, monopoly reduction is to be applied. However, the Authority, in its 23rd meeting dated 13.07.2015 decided not to apply monopoly reduction in the retail price fixation to encourage competition. In view of the above, the contention of the company is not relevant.

4. Examination:

4.1 The applicant has put forward two grounds for review of the order of NPPA fixing the retail price of its formulation. The first ground is that the retail price fixed is not commercially viable to the company as the price of an active pharmaceutical ingredient (API) of the formulation has become expensive by 100% compared to its price prevalent three years ago. The second ground is that the price fixed is not as per the paragraph 6(1)(b) of DPCO.

4.2 The first ground does not hold as the procedure of price fixation of a drug under DPCO does not take into account the prevalent price of the API of a drug. As per the provisions of DPCO, NPPA follows market based pricing exercise wherein there is no provision of consideration of cost based price exercise. Therefore, the issue raised by company has no merit.

4.3 The other ground is also not valid as NPPA has fixed the retail price of the formulation of company as per the provisions of DPCO. The retail price of a formulation is fixed as per provision in para 5(1) of DPCO, which states that *the retail price of the new drug available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4*. Since the subject new drug was available in the market, therefore, the retail price was fixed under paragraph 4(1). Para 6(1)(b) is not required for fixing the retail price of a medicine.

5. Decision:

In view of the foregoing examination, the contentions of the applicant are devoid of any merit. The application for revision of price under para 4, 5 & 6 of DPCO, 2013 stands rejected. However, the applicant may represent for price revision under para 19 before the Authority for examination.

Issued on this date, the 04th day of February, 2019.

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

Copy to:-

1. M/s KonTest Chemicals Limited, D.No.3-176/1, 1st Floor, Gowreswar Arcade, Gandimaisamma 'X' Road, Hyderabad-500 043.
2. The Member Secretary, 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. T.D., NIC for uploading the order on Department's Website.