No.31015/60/2023-Pricing (E-23871) 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 24.04.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 1434(E) dated 27.03.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the retail price of Telmisartan 40 mg + Cilnidipine 20 mg.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 25.07.2023 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 retail price of the above drug and hence may be directed to revise the same on the following grounds:

3.1. The applicant inadvertently missed reviewing the working sheet uploaded on the NPPA portal, but soon after the notification of the S.O. No. 1434(E) dated 27.03.2023, they reviewed the working sheet and submitted their concern/representation to NPPA on 31^{st} March, 2023.

3.2. In the working sheet, the PTR data of one of the competitor's product at SI. No. 4. i.e. M/s Ajanta Pharma Ltd was incorrectly taken as Rs 148.57 instead of Rs 200.00 due to which the retail price of the above referred formulation as notified vide NPPA S.O. No 1434(E) dated 27.03.2023 at S1. no. 22 has been incorrectly calculated on the lower side.

3.3. The data has also been revised/corrected by Pharmatrac in their database and the revised PTR of Rs. 200 is also reflected in their March database.

4. Gist of clarifications made by NPPA:

NPPA on the other side urged that:

4.1 As per para 9(4) of DPCO, the data considered for fixation of retail price is data available for the month ending immediately before six month of the application date (10.02.2023). Accordingly, PTR/MAT data for July, 2022 as appearing in Pharmatrac database of January 2023 was considered for the calculation of retail price. The PTR of

brand CINOD T for July, 2022 was Rs. 9.90 per tablet in Pharmatrac database of January 2023 and the same was considered for retail price fixation.

4.2 The draft worksheet was uploaded on NPPA's website on 10.03.2023 for 10 working days to invite comments from affected pharmaceutical firms in compliance to O.M. No. F. NO. 31015/44/2016-PI.I dated 11.07.2016 issued by Department of Pharmaceuticals. No representation was received from M/s Glenmark Pharmaceuticals Ltd or M/s Ajanta Pharma Ltd by 24.03.2023 i.e. within the prescribed time limit of 10 working days in this respect.

4.3 However, based on the additional submission of the company, NPPA sought confirmation from Pharmatrac with respect to PTR, MAT, Pack Size and Strength of CINOD T 20/40 MG Tablet of M/s Ajanta Pharma. Pharmatrac confirmed that the correct MRP is Rs. 280 and they have updated their database. Further, Pharmatrac has also provided the pack-shot /evidence of the changed MRP.

5. Examination:

5.1 NPPA had considered the PTR of brand CINOD T for calculation of retail price based on Pharmatrac database. No company has filed representation within the prescribed period of 10 working days to NPPA.

5.2 However, subsequently, Pharmatrac has confirmed that there was an error in the data with respect to CINOD T 20/40 MG Tablet of M/s Ajanta Pharma and they have since corrected PTR and MRP of the same. Therefore, in the present case, NPPA may relook into the issue and revise the retail price on the basis of extant provisions of DPCO 2013.

6. Decision:

In the backdrop of these facts, the case is referred back to NPPA for re-calculation of the retail price of the subject formulation for the applicant as per the extant provisions of DPCO 2013.

Issued on this, the 04th 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,

M/s Glenmark Pharmaceuticals Ltd. 7-D, Atmaram House, 1, Tolstoy Marg, New Delhi-110001.

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