

No. 31015/12/2019-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 03.08.2019 filed under para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Sun Pharma Laboratories Limited (hereinafter called the applicant) against notification SO 1687(E), dated 09.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Diltiazem 90mg capsules. The company filed the review application based on the direction / Order, dated 16.07.2019 passed by Hon'ble High Court of Delhi disposing of the WP (C) 6549/2019 filed by the company.

2. The applicant has filed the review application with the following contentions:-

- (i) The drug Diltiazem tablet was included in Schedule-I of DPCO 2013 as 30mg, 60mg and SR tablet 90mg, Injection 5mg/ml vide DoP's SO 701(E), dated 10.03.2016.
- (ii) The price of conventional Diltiazem 90 mg capsule was notified, but not for Diltiazem 90mg SR capsule. Therefore, the price of SR capsule was required to be fixed separately by considering the rate of similar products i.e. SR capsules only as per the procedure made in para 4, para 9 of DPCO.
- (iii) The NPPA has erroneously considered the PTR of company's two formulations, viz. Angizem CD 90 and Angizem DP 90 capsules as Rs 78.53 (against actual PTR 82.36), which is much lower than the applicable PTR of August, 2015.

2.2 The company also requested to direct the NPPA to withdraw Demand Notice, dated 8.5.2019 on Angizem CD 90 capsules and Demand Notice dated 22.5.2019 on Angizem DP 90 capsules, as the prices for these two formulations have not been notified.

3. NPPA 's Comments:

The grievance of company (at point (i) above) is a factual statement and offered no comments. As regards point (ii), while calculation of ceiling price, PTR of formulations other than immediate release formulations were considered. Therefore, the price fixed by NPPA is also applicable to the products Angizem DP 90 capsules

and Angizem CD 90 mg. of M/s Sun Pharma Laboratories Ltd. Regarding point (iii), NPPA considered the PTR as provided by Pharmatrac for the period of August 2015 while fixing the ceiling price vide SO 1687(E), dated 9.5.2016 and the company did not file review petition regarding the PTR of their products at that time.

4. Examination:

4.1 The drug Diltiazem tablet was included in revised Schedule-I (NLEM 2015) of DPCO 2013 as 30mg, 60mg and "SR tablet 90mg". However, in the price notification SO 1687(E), dated 9.5.2016, the NPPA notified the ceiling price of Diltiazem capsule 90mg and the phrase "SR" was omitted in the price notification, whereas while fixing the ceiling price, the NPPA has considered the PTR and MAT value of only Sustained Release (SR) formulations (other than immediate release formulations).

4.2 On clarification from the NPPA about the omission of words 'SR' in the price notification SO 1687(E), dated 9.5.2016, the NPPA admitted that words "SR" were inadvertently omitted in the price notification.

4.3 In view of the above, the NPPA has erred in notifying the ceiling price of Diltiazem capsule 90mg instead of SR Diltiazem 90mg capsule. Although it is fact that the NPPA, while notifying the ceiling price of Diltiazem capsule 90mg, has considered the data of formulations other than immediate release formulations and considered only SR formulations, but the fact remains that the notification was issued for Diltiazem 90mg capsules and not for SR Diltiazem 90mg capsules.

4.4 Considering the above facts, it is proposed that the NPPA needs to be directed to examine the case afresh and pass appropriate orders in respect of the subject formulation at S.No.19 of SO 1687(E), dated 09.05.2016.

4.5 The company has also requested to withdraw Demand Notice, dated 8.5.2019 on Angizem CD 90 capsules and Demand Notice, dated 22.5.2019 on Angizem DP 90 capsules. As the issue of Demand Notices for overcharging is within the purview of the NPPA, the same can also be examined by the NPPA as per provisions of the DPCO.

5. Decision:

"The NPPA is hereby directed to examine the case afresh and pass appropriate orders in respect of the formulation Diltiazem 90mg capsule at S.No.19 of SO 1687(E), dated 09.05.2016, within a period of thirty days of the issue of this order."

“As the issue of overcharging is within the purview of the NPPA, the NPPA is further directed to examine the matter of Demand Notices issued for overcharging as per provisions of DPCO.”

Issued on this date, the 24th day of July, 2020.

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

Copy to:-

1. M/s Sun Pharma Laboratories Limited, 8-C, 8th Floor, Hansalya Building, 15-Barakhamba Road, Connaught Place, New Delhi-110001.
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. Joint Secretary(Pharma), Shastri Bhawan, New Delhi for information.
7. T.D., NIC for uploading the order on Department's Website