

No. 31015/23/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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

Subject: Review application of M/s Dr. Reddy's Laboratories Limited against price fixation of "Omeprazole Capsule 10mg" vide NPPA order No. S.O. 248(E), dated 24.01.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 14.02.2017
2) NPPA notification under review S.O. 248(E), dated 24.01.2017
3) Record Note of discussions held in the personal hearing held in the matter on 22.08.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Dr. Reddy's Laboratories Limited (hereinafter called the petitioner) against notification S.O. No.248(E), dated 24.01.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Omeprazole Capsule 10mg.

2. The petitioner has contended as under:-

(i) **The worksheet for calculation of ceiling price of formulations notified vide S.O. 248 (E) dated 24th January, 2017 failed to consider all manufacturers of the aforesaid formulation having more than 1% Market Share** and wrongly considered company's formulation as a monopoly for Omeprazole 10 Mg capsules as listed in the first schedule of DPCO, 2013. DRL submits that "OCID CAPS 10 MG x 15" containing Omeprazole 10 Mg as manufactured by M/s. Zydus Cadila Ltd is also available in this category and has more than 1% market share and the price of this product should also be considered while fixing the ceiling price of formulations notified vide S.O. 248(E).

(ii) AND WHEREAS, Company submitted independent data from IMS-ORG to certify that both the above mentioned formulations have Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% Market Share.

(iii) AND WHEREAS, had NPPA correctly calculated the ceiling price of the aforesaid formulation as per the provisions of Para 4 of DPCO, 2013, after having taken into consideration "OCID CAPS 10 MG x 15" there would have been a reduction in the average price to retailer and therefore the condition under Para 6(1)(a) is not satisfied. Accordingly Para 6 is not applicable in the instant calculation of ceiling price.

(iv) AND WHEREAS, NPPA has calculated the price of Omeprazole Capsule 10 Mg under the provisions of Para 6 of DPCO, 2013 without taking into consideration "OCID CAPS 10 MG x 15" containing Omeprazole 10 Mg as manufactured by M/s. Zydus Cadila Ltd which also has more than 1% market share in this category.

Under the circumstances:

a. NPPA should calculate the ceiling price for OMEPRAZOLE 10 MG CAPSULES under the provisions of Para 4 of DPCO, 2013 since both the conditions under Para 6(1) are not satisfied as “OCID CAPS 10 MG x 15” containing Omeprazole 10 Mg as manufactured by M/s. Zydus Cadila Ltd. has not been taken into consideration.

b. NPPA must consider all formulations having Market share greater than 1% based on MAT of August, 2015.

c. As there would be a reduction in ceiling price upon correct calculation of ceiling price under para 4 after taking into consideration both OMEZ 10 mg capsules and OCID 10 mg capsules, NPPA cannot apply the provisions of Para 6 and notify a monopoly based ceiling price for the aforesaid formulation.

(v) Having been aggrieved by the fact that the captioned formulation was notified under Para 6 without taking into consideration “OCID CAPS 10 MG x 15” containing Omeprazole 10 Mg, , Company submitted that there has been an error in calculation of the notified ceiling price of Omeprazole 10Mg Capsules and accordingly the price so notified under S.O. 248 (E) dated 24th January, 2017 should be set aside until the correct ceiling price is calculated, considering the provisions of Para 4 of DPCO, 2013.

4. In view of the above, the company requested this Department as under:-

a. To consider and conclude that NPPA had erred in pricing of OMEPRAZOLE 10 MG CAPSULES under Notification no. S.O 248 (E) dated 24th January, 2017.

b. To direct NPPA to calculate ceiling price of OMEPRAZOLE 10 MG CAPSULES under the provisions of DPCO, 2013 after taking into consideration “OCID CAPS 10 MG x 15” containing OMEPRAZOLE 10 MG as manufactured by M/s Zydus Cadila Limited which also has a market share of more than 1% in this category, within 30 days.

3. Comments of NPPA:

Ceiling price of **Omeprazole Capsule 10mg** was notified as Rs. 1.96/capsule vide S.O. 248(E) dated 24.01.2017 and revised to Rs. 1.92/capsule vide S.O. 2058(E) dated 30.06.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Omeprazole Capsule 10mg**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has pointed out that NPPA has failed to consider all manufacturers of the aforesaid formulation having more than 1%	NPPA has considered the data provided by AIOCD-AWACS for month of August 2015. NPPA uploaded draft working

	market share and wrongly considered our formulation as a monopoly for Omeprazole Capsule 10mg . "OCID CAPS 10MG x 15" containing Omeprazole 10mg manufactured by M/s Zydus Cadila and having more than 1% market share is also available in the Pharma market which was not considered by the NPPA.	sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. Neither Dr. Reddy's Laboratories nor M/s Zydus Cadila submitted any representation against the proposed retail price uploaded on NPPA's website.
2.	Company submitted the copy of data from IMS-ORG to certify that both the above mentioned formulations have Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% market share.	NPPA has been consistently considering the data provided by AIOCD-AWACS for the month of August, 2015 for fixing the ceiling price of scheduled formulations.
3.	As per company view, NPPA correctly calculated the ceiling price of the aforesaid formulation as per the provisions of para 4 of DPCO, 2013 after having taken into consideration "OCID CAPS 10 MG x 15" there would have been a reduction in the average price to retailer and therefore, the condition under para 6(1)(a) is not satisfied. Accordingly, para 6 is not applicable in the instant calculation of ceiling price.	NPPA has applied para 6 of DPCO, 2013 based on the data provided by AIOCD-AWACS.
4.	NPPA has calculated the price of Omeprazole Capsule 10mg under the provisions of para 6 of DPCO, 2013 without taking into consideration "OCID CAPS 10 MG x 15" containing Omeprazole 10mg as manufactured by M/s Zydus Cadila which has more than 1% market share in this category.	Since, no company has submitted any representation based on draft working sheet, NPPA has fixed the ceiling price as per the data provided by AIOCD-AWACS.

III. Company has not challenged any notification in respect of **Omeprazole Capsule 10mg** in the Court.

4. Examination:

NPPA notified the ceiling price of Omeprazole Capsule 10mg vide SO 248(E), dated 24.01.2017 considering AIOCD-AWACS data for the month of August, 2015. The company, in its review application, stated that NPPA has not considered the market share of **Omeprazole 10mg** manufactured by M/s Zydus Cadila having more than 1% market share. In support of its claim, the company furnished only one sheet, containing IMS data of August, 2015, showing market share of 8.15% of formulation **Omeprazole**

10mg manufactured by M/s Zydus Cadila. No other documentary proof is submitted by the company in support of its claim. The single sheet submitted by the company cannot be considered as an authenticated document. Therefore, the request of the petitioner company cannot be considered and the review petition may be rejected.

5. **Government Decision:**

“M/s Dr. Reddy’s Laboratories Limited could not furnish any supporting documentary proof in support of its claim that the data of product Omeprazole 10mg, manufactured by M/s Zydus Cadila having MAT value of more than 1%, has not been considered for fixation of ceiling price of “Omeprazole Capsule 10mg. Therefore, the request of the petitioner company cannot be considered and the review petition stands rejected.”

Issued on this date, the 30th day of October, 2017.

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

To

1. M/s. Dr. Reddy’s Laboratories Limited,
Global Generics – India,
7-1-27, Ameerpet,
Hyderabad – 500016.
2. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. PS to Hon’ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department’s Website