

No. 31015/88/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

.....

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s Neon Laboratories Limited against price fixation of their formulation "Antinocin Injection containing Antinomycin D 0.5 MG" vide NPPA order No. S.O. 3089(E), dated 20.09.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 06.10.2017.
2) NPPA notification under review S.O. No.3089(E), dated 20.09.2017
3) Record Note of discussions held in the personal hearing on 14.11.2017.

1. This is a review petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Neon Laboratories Limited (hereinafter called the petitioner) against notification S.O. No.3089(E), dated 20.09.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Antinocin Injection containing Antinomycin D 0.5 MG.

2. The petitioner has contended as under:

I. National Pharmaceutical Pricing Authority (NPPA) issued a notification no S.O. 3089(E) dated 20/09/2017, fixing prices of Actinocin Injection containing Actinomycin D 0.5 MG at Sr. No. 2 under the provisions of para 6 of DPCO, 2013.

II. AND WHEREAS, the worksheet for calculation of ceiling price of formulations notified vide S.O. 3089(E) dated 20/09/2017 failed to consider company's formulation namely; Actinocin 0.5 MG Injection containing Actinomycin D Powder for Injection 0.5 mg having Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% Market Share. Against the total MAT value considered of Rs.0.04 lakhs, company's formulations has the MAT value of Rs.15.27 lakhs for August, 2015.

III. Company further submitted that ceiling price calculation under para 6 of DPCO, 2013 should be undertaken only in case of "no reduction in average price to retailer with respect to the prices to retailer of the schedule formulation" which was clearly not followed in the instance case. Company has objected against the draft worksheet for ceiling price calculation vide letter dated 15/09/2017.

Under the circumstances:

a. NPPA should revise the calculation of ceiling price for Actinomycin D Powder for Injection 0.5 mg under the provisions of para 4 of DPCO, 2013;

b. NPPA must consider company's formulations, having Market share greater than 1% based on MAT of August, 2015, for arriving at the ceiling price for captioned formulation;

c. All pack sizes/SKUs having Market share less than 1% must not be considered in the calculation of ceiling price under para 4.

IV. In view of above, company requested as under:

(i) To consider and conclude that NPPA had erred in pricing of D Powder for Injection 0.5 mg under S.O. 3089(E) dated 20/09/2017.

(ii) To direct NPPA to include company's formulation in revising the ceiling price of D Powder for Injection 0.5 mg under the provisions of Para 4 of DPCO, 2013.

(iii) Pass a speaking order in respect hereof.

(iv) Any other order in interest of this manufacturer.

3. **Comments of NPPA:**

I. Ceiling price of **Actinomycin D Injection 0.5mg** was notified as Rs. 287.76/pack vide S.O. 3089(E) dated 20.09.2017 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 **Actinomycin D Injection 0.5mg**. 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:-

SI No	Company's Grievances	NPPA's comments
1	<p>Company has stated that NPPA failed to consider their formulation namely Actinocin 0.5mg injection containing Actinomycin D powder for injection 0.5mg having Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% market share. NPPA considered MAT value of their product 0.04 lakhs against their claim 15.27 lakhs for August, 2015. Company also stated that they have submitted a certificate from chartered accountant in support of their claim.</p> <p>Company reiterated that as per para 4 of DPCO, 2013, Government shall include to retailer of all the brands and generic version of the medicine having market share more than or equivalent to 1% of the total market</p>	<p>NPPA notified ceiling price of Actinomycin D Injection 0.5mg as Rs. 287.76/pack vide S.O. 3089(E) dated 20.09.2017 considering the data provided by AIOCD-AWACS for the month of August, 2015.</p>

	turnover on the basis of Moving Annual Turnover of that medicine. Company is also of the opinion that para 6 is applicable only in case of no reduction.	
--	--	--

III. Company has not challenged S.O. No. 3089(E) dated 20.09.2017 in any Court.

4. The company was given a personal hearing, during which following further submissions were made:

- 1) AWACS-AIOCD data does not reflect sales from M/s. Neon labs as these are made directly to the government or institutions and not through the wholesaler / retailer supply chain.
- 2) The company representatives also shared a CA certificate clearing stating MAT for August 2015 at INR.15.27 lacs which is equivalent to 40% of the market share.
- 3) Further, the company submitted that their formulation sales have been incorrectly mentioned in the AWACS data and they shared a summary of invoices for the month of August 2015 in support of the same.

Thus, the company representatives once again prayed that their formulation Actinomycin D must be priced under Para 4 of DPCO 2013 and not Para 6.

4.2 NPPA representative stated that they have no further comments in addition to as stated above.

5. **Examination:**

On going through the calculation sheet, it is seen that NPPA has considered the MAT value of M/s Neon Laboratories Ltd. as Rs.3630/- only, representing 0.16% market share of total MAT value. Company stated that the actual MAT value of their product was Rs.15.27 lacs for the period September 2014 to August, 2015, which is more than 1% market share. The company stated that sales made directly to the government or institutions and not through the wholesaler / retailer supply chain does not reflect in AWACS-AIOCD data. In support of its claim of total MAT value, the company submitted CA certificate showing total MAT value for the period September, 2014 to August, 2015 as Rs.15.27 lacs.

6.2 As per para 4 of DPCO, 2013, the ceiling prices are being fixed by averaging the Price to Retailer of the scheduled formulation. NPPA consider the AWACS-AIOCD data, which does not reflect the sales made directly to the government or institutions. Presently, ceiling prices of all the scheduled formulations are being fixed by adopting the above formula. There is no separate provision in DPCO to consider the data of sales to government or institutions.

6.3 In view of the above, the request of the company to consider MAT value of their product's sales to government or institutions cannot be considered.

7. Government Decision:

“As per para 4 of DPCO, 2014, ceiling prices are being fixed by averaging the Price to Retailer of the scheduled formulation having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine. There is no separate provision in DPCO to consider the data of sales to government or institutions. Therefore, the request of the company to consider MAT value of their product’s sales to government or institutions cannot be considered, and the petition is rejected.”

Issued on this date, the 1st day of January, 2018.

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

To

- 1. M/s. Neon Laboratories Limited,
140, Damji Shamji Ind. Complex,
M. Caves Road, Andheri (E),
Mumbai-400 093.**
- 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**