# No. 31015/30/2018-Pricing GOVERNMENT OF INDIA MINISTRY OF CHEMICALS & FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

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A- Wing, Shastri Bhawan, New Delhi 110 001

#### <u>Order</u>

1. This is an order on an application dated 25.04.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Anot Pharma Private Limited (hereinafter called the applicant) against notification S.O. No.1461(E), dated 02.04.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) revising the ceiling prices of Silver sulphadiazine cream 1% w/w (5mg tube) and Ciprofloxacin Eye Ointment 0.3% w/w (3mg tube).

2. The petitioner has contended as under:-

2.1 The cost comparison of Ciprofloxacin Ophthalmic Ointment USP 0.3% and chloramphenicol ophthalmic ointment is as under:-

Cost of Ciprofloxacin (in Rs.)	Unit	Cost of Chloramphenicol (in Rs.)
1*1.14 = 1.14	1 gm tube	1*4.57 = 4.57
2*1.14 = 2.28	2 gm tube	2*4.57 = 9.14
3*1.14 = 3.42	3 gm tube	3*4.57 = 13.71
4*1.14 = 4.56	4 gm tube	4*4.57 = 18.28
5*1.14 = 5.70	5 gm tube	5*4.57 = 22.85

Packing material and base are same for both. Only active ingredient price differ by 0.03 paisa per gm.

2.2 Packing material cost for 1 gm is almost same. Details are as under:-

SI. No.	Description	Cost per tube in Rs.
1	Cost of tube with cap (materials, cap fitting, block making etc.)	2.95
2	Cost of unit pack	0.3
3	Cost of multi pack of 20 (Rs. 2.50 per piece)	0.125
4	Cost of outer c/n of 800 tubes (Rs. 30 per piece)	0.037
5	Excise duty 6%	0.21
	Total cost of packing material	3.622

This clearly shows that DPCO price for ciprofloxacin Ophthalmic Ointment is wrongly mentioned and cost of packing without (medicine processing cost, excise duty, freight and profit) is more than DPCO price.

2.3 Company further submitted that they are a MSME unit and are very much affected because of these DPCO prices which have no justification of cost to meet the actual expenses to produce said medicines.

## 3. <u>Comments of NPPA:</u>

3.1	The ceiling prices of formulations fixed by NPPA, are detailed below:-
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SI. No	Name of the Formulation	Company's product Composition	Notified Price (Rs)
1	Silver Sulphodizine cream 1% w/w	Each tablet contains: 5 gm tube	Rs 0.28 per gm
2	Ciprofloxacin Eye ointment 0.3% w/w	Each tablet contains: 3 gm tube	Rs 1.06 per gm

3.2 NPPA fixed ceiling price Rs. 0.27 per gm for Silver Sulphodizine cream 1% vide S.O. 3089(E) dated 20.09.2017 and Rs. 1.04 per gm for Ciprofloxacin Eye ointment 0.3% vide S.O. 3431 (E) dated 10.11.2016 under NLEM 2015 of DPCO, 2013. Petitioner company did not file review application against S.O. 3089(E) dated 20.09.2017 and S.O. 3431 (E) dated 10.11.2016. NPPA issued the notification No. SO 1461 (E) dated 02.04.2018 just to give effect of WPI on the earlier applicable ceiling price and therefore review against this notification is not sustainable.

3.3 As far as the company's claim that they are MSME unit, it is clarified that DPCO does not differentiate between MSME, small scale unit and large scale unit. Further, there is no provision in DPCO to consider the cost and actual expenses for fixation of ceiling price. NPPA consider market base data in order to arrive at the ceiling price as per para 4 and 6 of DPCO, 2013.

### 4. Examination:

NPPA has notified SO 1461(E), dated 2.4.2018 only for giving Annual Wholesale Price Index @3.43812% increase effective from 1.4.2018 to the scheduled formulations.

4.2 The ceiling price of Silver Sulphodizine cream 1% had been fixed by NPPA vide S.O. 3089(E) dated 20.09.2017. Similarly, ceiling price for Ciprofloxacin Eye ointment 0.3% was fixed vide S.O. 3431(E) dated 10.11.2016 under NLEM 2015 of DPCO, 2013. If the company was not satisfied with the price fixation of these formulations, the review applications should have been filed when the ceiling prices were fixed and notified by NPPA. SO 1461(E), dated 2.4.2018 is notified just to give effect of WPI on the earlier applicable ceiling prices and therefore review against this notification is not sustainable. Therefore, the review application deserves to be rejected.

4.3 As regards other grievance of the company about being MSME unit, DPCO does not differentiate between MSME, small scale unit and large scale unit. Further, there is no provision in DPCO to consider the cost and actual expenses for fixation of ceiling price. NPPA consider market base data in order to arrive at the ceiling price as per para 4 and 6 of DPCO, 2013. Hence, there is no merit in the grievance of the company.

### 5. <u>Decision:</u>

"NPPA notified SO 1461(E), dt.2.4.2018 only to give WPI increase effective from 1.4.2018 to all the scheduled formulations and not meant to re-fix the ceiling price of any formulation. Therefore, the grievances raised by the company have got no relevance and the application stands rejected."

Issued on this date, the 2<sup>nd</sup> day of July, 2018.

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

Copy to:-

- 1. M/s Anod Pharma Private Limited, E-20, Panki Industrial Area, Site-I, Kanpur-208 022.
- 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