

**No. 31015/2/2017-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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

**Subject: Two Review Applications of M/s Cipla Ltd. against price fixation of “Azithromycin Powder for Injection 500 mg and Lamivudine 150mg+Nevirapine 200mg+Stavudine 30mg” vide NPPA order No. S.O. 4128(E), dated 22.12.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Two Review applications dated 19.01.2017  
2) NPPA notification under review S.O. 4128(E), dated 22.12.2016  
3) Record Note of discussions held in the personal hearing held in the matter on 28.02.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Cipla Ltd. (hereinafter called the petitioner) against notification S.O. No.4128(E), dated 22.12.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Azithromycin Powder for Injection 500 mg and Lamivudine 150mg+Nevirapine 200mg+Stavudine 30mg

2. The petitioner has contended as under:-

- I. AND WHEREAS, the worksheet for calculation of ceiling price of formulations notified vide S.O. 4128 (E) dated 22<sup>ND</sup> December, 2016, NPPA has erred by considering their formulations “AZIPRO 500 MG INJECTION 10 ML”, “TRIOMUNE JUNR 150/30/200 MG TABLET 60”, “TRIOMUNE BABY 150/30/200 MG TABLET 60” and “TRIOMUNE 150/30/200 MG TABLET 60” having market share of less than 1% in the calculation of ceiling price for the aforesaid formulations.
- II. AND WHEREAS, Para 4 of DPCO, 2013 clearly states that the government shall include the market shares of only generics/ Brands SKU-wise and not Company wise MAT percentages to fix the ceiling prices.
- III. Under the circumstances:
  - a. NPPA should revise the ceiling price for above said formulations as per the provisions of Para 4 of DPCO, 2013.
  - b. All pack sizes/SKUs having Market share less than 1% must not be considered in the calculation of ceiling price under Para 4.
  - c. Their formulations namely; “AZIPRO 500 MG INJECTION 10 ML” “TRIOMUNE JUNR 150/30/200 MG TABLET 60”, “TRIOMUNE BABY 150/30/200

MG TABLET 60” and “TRIOMUNE 150/30/200 MG TABLET 60” must not be considered in the calculation of ceiling price for aforesaid formulations.

IV. Having been aggrieved by the errors in calculation of ceiling price and subsequent notification of incorrect ceiling price for the aforesaid formulation, Cipla files this Review Petition under Para 31 of the Drugs (Prices Control) Order, 2013 against notification no. S.O. 4128 (E) dated 22<sup>ND</sup> December, 2016 and **requests a speaking order in the matter**. As the petitioner is submitting this review petition against the said S.O. 4128 (E) dated 22<sup>ND</sup> December, 2016 for non-compliance with the provisions of para 4 of DPCO, 2013 and the review petition is being filed with the Department of Pharmaceuticals. Consequently, the Review Petition under Para 31 of Drugs (Prices Control) Order, 2013 is filed within the prescribed time limit.

V. In view of above, company requested this Department:-

a. To consider and conclude that NPPA had erred in pricing of above said formulations under Notification no. S.O 4128 (E) dated 22<sup>ND</sup> December, 2016.

b. To consider revision of Ceiling price in line with the provisions of Para 4 and rectify the same within 15 days.

c. Pass a speaking order in respect hereof.

d. Any other order in interest of this manufacturer.

Comments of NPPA:

In this regard, it is stated that:-

| Sl. No.   | Company Grievances   | NPPA comments  |
|---|--|--|
| <b>1. Azithromycin Powder for Injection 500mg</b> |  |  |
| 1.  | Company has stated that NPPA has considered the PTR & MAT value of their brand AZIPRO 500mg Injection 10ml having market share of less than 1% in the calculation of ceiling price for aforesaid formulation. Company has submitted the copy of review order no 31015/40/2015-PI.I dated 29.11.2016 in support of their claim. | DOP vide letter no. F. No. 31015/44/2016-PI.I dated 11.7.2016 gave the following, directions: <i>“NPPA to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceuticals firms. Only after taking into account the comments or any additional data thus received within the given time period, the</i> |

|  |   |   |
|--|---|---|
|  |   | <p><i>NPPA shall finalize the Ceiling and the Retail Prices. This issues with the approval of Hon'ble Minister (Chemicals &amp; Fertilizers)". Accordingly, NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. <b>M/s Cipla Limited <u>did not make any representation against the proposed ceiling price uploaded on NPPA's website.</u></b></i></p>  |
| 2.   | Inclusion of the PTR of AZIPRO 500mg Injection 10ml is against the para 4 of DPCO, 2013.  | NPPA has considered the PTR and MAT value of AZIPRO 500mg Injection 10ml as provided by pharma-trac for the month of August, 2015 and on the principles as decided by Authority in its 27 <sup>th</sup> Authority meeting held on 29.3.2016.  |
| 3.   | NPPA should not considered PTR of AZIPRO 500mg injection 10ml in the calculation of ceiling price for this formulation  | NPPA has considered the PTR and MAT value of the formulations a & provided by pharma-trac for the month of August, 2015 & on the principles as decided by Authority in its 27 <sup>th</sup> Authority meeting held on 29.3.2016. Hence issue raised by company is not tenable.  |
| <b>2. Lamivudine 150mg + Nevirapine 200mg + Stavudine 30mg</b> |   |   |
| 1.   | Company has stated that NPPA has considered the PTR & MAT value of their brand " <b>TRIOMUNE JUNR 150/200/30 Tablet 60</b> ", " <b>TRIOMUNE BABY 150/200/30 Tablet 60</b> " and " <b>TRIOMUNE 150/200/30 Tablet 60</b> " having market share of less than 1% in the calculation of ceiling price for this formulation. Company has submitted the copy of review order no 31015/40/2015-PI.I dated 29.11.2016 in support of their claim. | DOP vide letter no. F. No. 31015/44/2016-PI.I dated 11.7.2016 gave the following, directions: " <i>NPPA to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceuticals firms. Only after taking into account the comments or any additional data thus received within the given time period, the NPPA shall finalize the Ceiling and the Retail Prices. This issues with</i> |

|    |   |  |
|----|---|--|
|    |   | <i>the approval of Hon'ble Minister (Chemicals &amp; Fertilizers)". Accordingly, NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. <b>M/s Cipla Limited did not make any representation against the proposed ceiling price uploaded on NPPA's website.</b></i> |
| 2. | Inclusion of the PTR of "TRIAMUNE JUNR 150/200/30 Tablet 60", "TRIAMUNE BABY 150/200/30 Tablet 60" and "TRIAMUNE 150/200/30 Tablet 60" is against the para 4 of DPCO, 2013. | NPPA has considered the PTR and MAT value of "TRIAMUNE JUNR 150/200/30 Tablet 60", "TRIAMUNE BABY 150/200/30 Tablet 60" and "TRIAMUNE 150/200/30 Tablet 60" as provided by pharma-trac for the month of August, 2015 & on the principles as decided by Authority in its 27 <sup>th</sup> Authority meeting held on 29.3.2016.  |

3. During the personal hearing on 28.02.2017, the representatives of the company reconfirmed that the aforesaid formulations need to be priced again in accordance with para 4(i) of DPCO, 2013 after considering only those brands with market value greater than 1%. The number of brands to be excluded from calculation of ceiling price as per company submission is as follows:-

| Formulation name  | Number of brands to be excluded |
|---|---------------------------------|
| Lamivubine 150 mg + Nevirapine 200 mg + Stavudine 30mg tablet | 3                               |
| Azithromycin 500 mg power for injection                       | 3                               |

Further, the company representative also stated that for Lamivubine 150 mg + Nevirapine 200 mg + Stavudine 30mg tablet, NPPA has also erred by considering Triamune JUNR and Triamune BABY in the calculation of ceiling price whereas these non-scheduled formulations have a different composition as stated below:-

- (i) Triamune JUNR contains Lamivubine 60 mg + Nevirapine 100 mg + Stavudine 12mg tablet
- (ii) Triamune BABY contains Lamivubine 30 mg + Nevirapine 50 mg + Stavudine 6mg tablet

Thus, the price for Lamivubine 150 mg + Nevirapine 200 mg + Stavudine 30mg tablet must be revised to comply with the provisions of para 4 and definition of Schedule formulation under para 2 of DPCO 2013.

On the issue regarding inclusion/exclusion of brands having 1% or more, NPPA representative further stated that they have been following the existing practice in fixing the ceiling price as per the decisions of 27<sup>th</sup> Authority Meeting of NPPA held on 29.03. 2016. NPPA also stated that even after NPPA uploaded the draft working sheet in its website prior to notification of ceiling price to seek representation from the aggrieved companies based on the DOP's letter no. F.No. 31015/44/2016-PI.I dated 11.7.2016, M/s Cipla Ltd. did not make any representation at that time. NPPA representative further stated that NPPA may re-examine the issue of inclusion/exclusion of various brands/ products after receipt of relevant document/information and verification of the same.

#### **4. Examination:**

The petitioner company has challenged the NPPA S.O. 4128(E), dated 22.12.2016 for price fixation of their formulations **Azithromycin Powder for Injection 500 mg and Lamivudine 150mg+Nevirapine 200mg+Stavudine 30mg** and the main contention of the company is that while fixing the ceiling prices of the aforesaid formulations only those brands that have more than 1% market share have to be considered.

On examination, it is found that NPPA has erred in calculating ceiling price as per para 4 of DPCO, 2013, which reads as under :-

#### ***“4. Calculation of ceiling price of a scheduled formulation***

***(1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the First Schedule shall be calculated as under:-***

***Step 1: First the Average price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:-***

***Average Price to Retail P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine 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)/(Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine).”***

It clearly mentions that the medicines are to be taken for calculation. The principles applied by NPPA on the basis of decision of their 27<sup>th</sup> Authority Meeting go beyond what is mentioned in DPCO. Hence, NPPA may be directed to refix the ceiling price in accordance with the provisions of DPCO. The DPCO does not recognise a company for average PTR but only medicines/ formulations. Thus, only

those formulations are to be considered, which are having MAT value of more than 1% market share. On going through the calculation sheet of each of the formulations, it is observed that the number of formulations which are to be considered having more than 1% market share and number of formulations to be excluded, as per table given below:-

| <u>Formulation name</u>                                 | <u>Number of brands to be considered having more than 1% market share</u> | <u>Number of brands to be excluded</u> |
|---|---|--|
| <b>Azithromycin Powder for Injection 500 mg</b>         | 3   | 1                                      |
| <b>Lamivudine 150mg+Nevirapine 200mg+Stavudine 30mg</b> | 6   | 3                                      |

In view of the above, NPPA may be directed to refix the ceiling prices of the formulations by considering only those medicines / formulations having MAT value of more than 1% market share, as DPCO does not recognise a company for average PTR but only medicines / formulations.

5. Government Decision:

**“NPPA is hereby directed to refix the ceiling prices of the formulations Azithromycin Powder for Injection 500 mg and Lamivudine 150mg+Nevirapine 200mg+Stavudine 30mg by considering only those medicines / formulations having MAT value of more than 1% market share, as DPCO does not recognise a company for average PTR but only medicines / formulations.”**

Issued on this date, the 18<sup>th</sup> day of April, 2017.

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

To

1. M/s. Cipla Ltd.,  
Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg,  
Lower Parel, Mumbai-400013.
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