

No. 31015/29/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: Review application of M/s Alembic Pharmaceuticals Ltd. against price fixation of "Azithromycin Tablets 250 mg and 500 mg" vide NPPA order No. S.O. 1686(E) dated 09.05.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 19.05.2016
2) NPPA notification under review S.O. No.1686(E) dated 09.05.2016
3) Record Note of discussions held in the personal hearing held in the matter on 23.6.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Alembic Pharmaceuticals Ltd. (hereinafter called the petitioner) against notification S.O. No.1686(E) dated 09.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Azithromycin Tablets 250 mg and 500 mg Tablet.

2. The petitioner has contended as under:

- i. Fixation of ceiling price of Azithromycin 250 & 500 mg tablets on May 09, 2016 after it was once done on 2nd March, 2016 (meant for period of one year starting from April 01, 2016 till 31st March, 2017) (**i.e. change within span of less than 40 days**) is unreasonable. In addition, when there is **no change in the aforesaid formulations in DPCO 2016 from what was originally envisaged in DPCO 2013**, the question of fixation of ceiling price does not arise by virtue of paragraph 17 read with paragraph 18 of the DPCO.
- ii. NPPA failed to appreciate the correct position of law, wherein **paragraphs 17 and 18 of the DPCO must be read together and cannot be read in isolation**. It is pertinent to mention here that the combined reading of the aforesaid paragraphs allow the ceiling price fixation only to the extent for medicines which have been **added** in the revised NLEM. The price of existing medicines cannot be revisited **till the lapse of five years** from the last fixation. Hence the Notification itself ought to be set aside/quashed.
- iii. Without prejudice to the fact that the impugned notification is not sustainable under paragraph 18(i) read with paragraph 17 of the DPCO, company submitted that:

- NPPA has wrongly calculated the ceiling price of Azithromycin 250 & 500 mg tablet by considering PTR of **discontinued products**,
 - the products which were **never launched** in market were considered, and
 - the products with **wrong pack sizes** were considered.
- iv. The abovementioned discrepancies have been highlighted by the applicant in the review application for immediate reference and are not repeated here for brevity.
- v. The NPPA has wrongly considered **Generics and branded medicines having market share less than 1%** in contradiction to the law laid down in step 1 of paragraph 4(1) of the DPCO.
- vi. The NPPA has ignored the actual situation in the industry, wherein **Retailers margin on PTR is 25% unlike 16% Retailers margin considered by the NPPA**. Therefore, while calculating the ceiling price, NPPA disregarded the actual situation and practice prevailing in the Indian pharmaceutical industry.
- vii. The NPPA ignored the absence of **one standard PTR** in respect of Generic Azithromycin 250 mg & 500 mg tablets. Consequently, the NPPA ignored other prevalent and significantly higher PTR figures while deciding the ceiling price which caused grave injustice to the applicant.

In view of the above submissions, the company prayed that the impugned Notification dated 9th May, 2016 does not stand in eyes of law and if sustained, would cause grave injustice to the applicant. Hence, same ought to be set aside / quashed.

Comments of NPPA:

- NPPA representative mentioned that Azithromycin 250 mg and 500 mg tablet was scheduled formulations under DPCO 2013 and DPCO 2016. NPPA has fixed ceiling price for 250 mg at Rs.10.26 vide S.O. 2052(E) dated 5.07.2013 and the same was revised to Rs. 10.91, 11.33 and 11.02 vide S.O. 1156(E) dated 28.04.2014, S.O. No. 619(E) and S.O. 644Z(E) dated 02.03.2016 on account of WPI impact which was supposed to be effective from 1st April 2016. In the same way, the price of Azithromycin 500 mg tablet, the ceiling price was fixed at Rs. 19.86, 20.51, 21.81, 22.65, and Rs. 22.04 vide SO 644 E dated 2nd March 2016 which was supposed to be effective till 31st March 2017. DOP has amended scheduled I of DPCO 2013 vide S.O. No. 701(E) dated 10th March, 2016 substituting DPCO 2013 by DPCO 2016 under para 17 and 18 of DPCO 2013, NPPA was mandated to refix the price of these formulations. Therefore, again NPPA has fixed ceiling price at Rs. 9.06 for Azithromycin 250 mg tablet and Rs. 17.83 for Azithromycin 500 mg tablet vide S.O. 1686(E) dated 9th May, 2016 as per Para 4, 10,11, 14, 16, 17 and 18 of DPCO 2016.

- NPPA is mandated to ensure the availability of scheduled formulation at affordable rate therefore price fixation of the formulation is within the provisions of DPCO 2016.

3. The company was given a personal hearing on 23rd June, 2016, during which the following submissions were made :

Mr Ajay Desai started the discussion by giving a background of the circumstances and events that led to the present hearing. He pointed out the following:

- WPI price revision was notified *via* notification no.644(E) dated 2nd March, 2016 (w.e.f. 1st April, 2016 upto 31st March, 2017) which included medicine Azithromycin 250mg and 500mg. The aforesaid notification was diligently followed by the company as directed by NPPA. However, NPPA renotified the prices of same formulation *via* notification no. 1686 (E) dated 9th May, 2016 and further reduced a price by approx..20%.
- The rationale for said reduction on 9th May, 2016 was unjustified and without any basis either on facts prevailing in the market or by law under DPCO.
- He further specifically pointed out that there is no change in respect of our formulation i.e. Azithromycin 250mg and 500 mg. which was included in DPCO, 2013 as well as DPCO, 2016 notified *via* SO No.701 (E) dated 10th March, 2016.

Mr. Vivek Ranjan added to Mr. Desai's submission by stating the following:

- NPPA is reading Para18 as a stand-alone paragraph which is not correct reading of law under DPCO. Para 17 and 18 of DPCO needs to be read harmoniously to conclude that NPPA has power to revise the ceiling price of scheduled drugs on revision of NLEM.
- NPPA has power to revise ceiling price of only those drugs which have been included freshly in the schedule 1 in consequence of revision under Para 17 of the DPCO. He submitted that the revision of the ceiling price of the existing product under paragraph 18 of the DPCO can only be done after five years from the last fixation.
- The aforesaid submission is clear in view of the fact that Para 17 of DPCO categorically mentions the fixation of ceiling price for the medicine(s) which have been **added** (emphasis supplied) in the first schedule. It is pertinent to mention here that there is no change in Azithromycin 250 mg and 500 mg (Azithral) tablets from DPCO 2013 to DPCO 2016.

Mr. Ajay Desai continued his submission by bringing the following facts:

- The calculation of ceiling price under Para 4 has been erroneously done in as much as certain medicines were not in market at the time for which MAT has been considered for calculation of the ceiling price (i.e. August, 2015).
- To strengthen his aforesaid submission Mr. Desai brought the following examples:

- Brand name AZEEMUNE 500 manufactured by Cipla Ltd. which has been considered in working sheet by NPPA, was discontinued from September, 2013 which is supported by Cipla Ltd. on their letter head. It is pertinent to note that the impact due to incorrect calculation of ceiling price is Rs 0.34.
 - Whereas AZILIDE 250 DT of Micro Labs Ltd. considered in working sheet by NPPA has never been manufactured or marketed by Micro Labs Ltd (supported by Micro Labs Ltd on their letter head). It is pertinent to note that the impact due to incorrect calculation of ceiling price is Rs 0.06.
 - Working sheet discloses wrong pack size e.g. MICROBACT 500 of Micro Labs Limited is of 3's whereas working sheet mentions the same to be of 6's as well as that of 3's. Mr. Desai submitted that the pack size of 6's is erroneously included and needs to be deleted to arrive at correct ceiling price. It is pertinent to note that the impact due to incorrect calculation of ceiling price is Rs 0.28.
 - In view of the above, we request the learned Deputy Secretary to kindly direct the NPPA to revise the price to rectify the above discrepancy.
- Mr. Desai brought the attention of learned Deputy Secretary to Para 4 of the DPCO and stated the following:
- In step 1 of Para 4(1) of DPCO only those prices to retailer (PTR) of all the brands and generic versions of the medicine having market share more than or equal to 1% of total market turnover on the basis of MAT is to be considered while calculating ceiling price.
 - However, NPPA while following the step 1 of Para 4(1) has considered the medicine with less than 1% and considered the 1% market share at the company level which ought to have been considered vis-à-vis specific brand and generic medicine. It is pertinent to note that the aforesaid clubbing defeats the 1% criteria under step 1 of par 4(1) while also bringing down the ceiling price substantially.
 - At this juncture Mr. Ranjan brought the attention of the learned secretary to the fact that DPCO defines "brand" and "generic version of a medicine" under two different heads of the paragraph 2 of the DPCO. In view of this, he submitted that the expression "brands and generic versions of medicine" in the step 1 of the paragraph 4(1) should be read disjunctively and the 1% criteria under the aforesaid step should be individually met by "brand" and "generic versions of medicine" and not in combination.
 - It is pertinent to mention here that the impact on the ceiling price per tablet for the 500 mg tablet and 250 mg tablet of Azithromycin due to abovementioned discrepancy are Rs. 1.95 and Rs. 0.66 respectively which is substantial in nature. In view of the above, we request the learned Deputy Secretary to kindly direct the NPPA to revise the price to rectify the above discrepancy.

Mr. Ajay Desai continues his submission by bringing the current scenario:

- NPPA's calculation considers Retailers margin as 16% (which is ideally 13.80% of ceiling price) whereas the actual retailer margin as per Industry practise is

20% (which is ideally 25% of ceiling price). Hence, the ceiling price ought to be higher, when calculated with margin of 20%.

- The PTR considered by NPPA for deriving ceiling price as indicated in Working Sheet of NPPA (forming basis of ceiling price notified on May 09, 2016) varies from the actual PTR calculation as per actual prevailing business practises of Pharma Industry. It is pertinent to note that NPPA considers retailer margin as 16% on PTR due to which the ceiling price is considerably slashed. He submitted it is clear that the industry works at a minimum threshold of 25% margin (on PTR) and consideration of 16% margin (on PTR) under DPCO would lead to grave injustice to the pharmaceutical industries. It is pertinent to mention here that the impact on the ceiling price per tablet for the 500 mg tablet and 250 mg tablet of Azithromycin due to abovementioned discrepancy are Rs. 1.42 and Rs. 0.73 respectively. In view of the above, we request the learned Deputy Secretary to kindly direct the NPPA to revise the price to rectify the above discrepancy.
- Mr. Desai stated the fact of non-prevalence of one standard PTR in respect of AZITHROMYCIN 250 & AZITHROMYCIN 500. He added that, for single product, different PTR is reported at different price point. Therefore, the PTR reported by NPPA in respect of brand(s) is inaccurate and same cannot be validated. In view of the above, he reiterated that the reported price point is inaccurate and same cannot be validated due to non-prevalence of one standard PTR. Mr Desai further brought the attention of the learned Secretary to the letter provided by AWACS, wherein AWACS validated the presence of different PTR is reported at different price point.
- It is pertinent to mention here that the impact on the ceiling price per tablet for the 500 mg tablet and 250 mg tablet of Azithromycin due to abovementioned discrepancy are Rs. 1.59 and Rs. 0.56 respectively. In view of the above, it is prayed to the learned Deputy Secretary that the NPPA should be directed to rectify the abovementioned discrepancy and correct the ceiling price accordingly.

NPPA comments:

- NPPA representative mentioned that Azithromycin 250 mg and 500 mg tablet was scheduled formulations under DPCO 2013 and DPCO 2016. NPPA has fixed ceiling price for 250 mg at Rs.10.26 vide S.O. 2052(E) dated 5.07.2013 and the same was revised to Rs. 10.91, 11.33 and 11.02 vide S.O. 1156(E) dated 28.04.2014, S.O. No. 619(E) and S.O. 644Z(E) dated 02.03.2016 on account of WPI impact which was supposed to be effective from 1st April 2016. In the same way, the price of Azithromycin 500 mg tablet, the ceiling price was fixed at Rs. 19.86, 20.51, 21.81, 22.65, and Rs. 22.04 vide SO 644 E dated 2nd March 2016 which was supposed to be effective till 31st March 2017. DOP has amended scheduled I of DPCO 2013 vide S.O. No. 701(E) dated 10th March, 2016 substituting DPCO 2013 by DPCO 2016 under para 17 and 18 of DPCO 2013, NPPA was mandated to refix the price of these formulations. Therefore, again NPPA has fixed ceiling price at Rs. 9.06 for Azithromycin 250 mg tablet and Rs. 17.83 for Azithromycin 500 mg tablet vide S.O. 1686(E) dated 9th May, 2016 as per Para 4, 10,11, 14, 16, 17 and 18 of DPCO 2016.

- NPPA is mandated to ensure the availability of scheduled formulation at affordable rate therefor price fixation of the formulation is within the provisions of DPCO 2016.

4. Examination:

It is seen that the products were in the category of Scheduled Drugs on the basis of NLEM 2011 and also in NLEM 2015. With the revision of Schedule 1 on the 10th March, 2016, incorporating NLEM 2015, these products continued to be in Schedule 1. NPPA has revised the ceiling prices of these products as per provision of para 18(i), which states that:

“The revision of ceiling prices on the basis of moving annual turnover value shall be carried out –

- (i) as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order, whichever is earlier.”

In this particular case, revision of ceiling price has been done by NPPA on the basis of revision of NLEM and consequent revision in Schedule 1. NPPA is fully within its powers to revise the ceiling prices. The contention of the petition has no justification and may be rejected.

NPPA representative has, however, mentioned that the matter regarding submission of the petitioner company on rectification of PTR taken while fixing the price of the aforesaid formulation is under examination in NPPA.

5. Government Decision:

In view of the above, the petition of the company seeking to quash/ set aside the NPPA SO No.1686(E) dated 9.5.2016 stands rejected. However, any relevant data being furnished by the petitioner company shall be examined by NPPA on merits and refix the ceiling price of the formulations within one month of the issue of this Order.

Issued on this date, the 30th day of August, 2016.

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

To

- 1. M/s. Alembic Pharmaceuticals Ltd.
Alembic Road,
Vadodra – 390 003.**
- 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**