

No. 31015/43/2016-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 Alkem Laboratories Ltd. against price fixation of “Cefotaxime 1 gm injection” vide NPPA order No. S.O. 1817(E) dated 18.05.2016 and SO 1405(E), dated 12.4.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 07.06.2016
2) NPPA notification under review S.O. 1817(E) dated 18.05.2016 and SO 1405(E), dated 12.4.2016
3) Record Note of discussions held in the personal hearing held in the matter on 26.07.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Alkem Laboratories Ltd. (hereinafter called the petitioner) against notification S.O. 1817(E) dated 18.05.2016 and SO 1405(E), dated 12.4.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Cefotaxime 1 gm injection.

2. The petitioner has contended as under:

- a. NPPA is yet to act on the rectification of the errors that have crept in while fixing the ceiling prices of the above formulations. **It is pertinent to note that they have implemented the revised ceiling prices as notified by the aforesaid price fixation Notifications dated 12th April, 2016 and 18th May, 2016 and intimated NPPA and the State FDAs accordingly.**
- b. The above formulation was introduced for the first time in the revised NLEM 2015. They submitted that the fixation of the ceiling price of Cefotaxime 1 gm has not been exercised in accordance with the letter and spirit of the DPCO particularly terms of the provisions of paragraphs 4 and 18 of the DPCO read with the National Pharmaceutical Pricing Policy, 2012 (NPPP-2012) issued on 07.12.2012.
- c. It is apparent that the aforesaid Notification S.O. 1817(E) & S.O. No. 1405(E) has being issued for ‘fixing’ for the first time the Ceiling Prices in respect of the formulations mentioned therein, which includes our subject formulation, in view of their inclusion in the revised NLEM 2015. Since the Ceiling price is fixed in respect of the subject formulation for the first time, the concept of ‘revision’ cannot apply and consequently the provisions of paragraphs 16 or 18 – both of which deal with ‘revision’ cannot be attracted.
- d. They submitted that the ceiling price of the subject formulation must be fixed only in accordance with paragraph 4 of DPCO. **Once an exercise is conducted under**

paragraph 4, the question of applying any effect of the WPI change cannot arise. In fixing the ceiling price of the subject formulation, however, **the Government has applied a WPI reduction**, which they submitted is unfair, unjustified and contrary to the scheme of the DPCO. They submitted that such reduction must not be applied.

- e. Without prejudice to the aforesaid, they further submitted that even the ceiling price that has been re-fixed is totally unrealistic and arrived at without taking into account the widely available information in the public domain. The Government is well aware that in the pharmaceutical Industry the actual Retailers' Margin gets fixed based on the relative negotiating capacities of the manufacturers and the trade associations of which such retailers are members. At present, in most cases this Retailers margin has been fixed at 20% of the Maximum Retail Price (MRP), which works out to 25% of the PTR, as opposed to the Retailers' Margin of 16% of the PTR which is used for calculating the ceiling price.
- f. Without prejudice to what is stated above, while going through the working sheet uploaded by the NPPA (for S.O. No. 1405), they identified the working is not based on company level MAT %, due to which some products' PTR is not considered in ceiling price calculation. Based on company level MAT % 2 brand of Lupin which were not considered in working turns eligible for consideration. Similarly erstwhile Biochem which was taken over by Zydus is shown separately in working. Both the company being same needs to be considered as one part, due to which the Gencel of Zydus would also be considered for computation.
- g. **If the aforesaid errors are rectified, the ceiling price in respect of Cefotaxime 1 gm would work out to 47.70 per vial.**

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 31.85 per pack as per the provisions of DPCO, 2013.
 - (ii) Earlier ceiling price of Rs. 31.24 per pack was fixed vide S.O. 1405(E) dated 12.4.2016 as per data provided by pharma-trac for the Period August 2015 and the same was revised to Rs. 31.85 based on the representation.
 - (iii) The company's representation has been disposed vide letter dated 15.7.2016
3. The company was given a personal hearing on 26th July, 2016, during which the following submissions were made :

The company representatives confirmed that they have implemented the price notification and submitted Form-V to NPPA. The company made the following further submissions—

- I. Being a price fixation, para 16 is not applicable. Hence, WPI should not be considered while working the ceiling price.

- II. In the working sheet, NPPA has considered the prices at SKU level whereas the company's submission to consider at company level. Therefore, two products of Lupin also should be considered in working of ceiling price.
- III. Similarly, Zydus and Biochem being a same company, Gencef 1 gm of Zydus should also be considered while working the ceiling price.
- IV. During the discussions, letter dated 15th July, 2016 was mentioned as issued by NPPA, has not been received by the company.

NPPA Representative clarified that ceiling prices are fixed under NLEM 2015 as per the provisions of para 4, 10, 11, 14, 16, 17 & 18 of DPCO 2013 based on the decision of the Authority so as to pass the impact of WPI to manufacturers and consumers. The representation made by M/s Alkem Laboratories regarding II & III above was already decided by the Authority and intimated to the company. Copy of the intimation letter was handed over to the representatives of the company.

4. Examination:

Cefotaxime 1gm. Injection was a non-scheduled drug till 10.03.2016 and it became scheduled drug for the first time as per Government of India Notification No.701(E) dated 10.03.2016. The ceiling price of the product was fixed for the first time vide NPPA Notification dated 12.04.2016 (page.1a/cor). The price of the product was re-fixed by NPPA vide their Notification dated 18.05.2016 based on the representation of the petitioner company. The petitioner company has challenged both the notifications of NPPA on Para 16 is not applicable in such cases of price fixation. Hence Wholesale Price Index (WPI) should not be considered while working the ceiling price for the product.

Para 16 (1) of DPCO, 2013 reads as under:

“The Government shall revise the ceiling prices of scheduled formulations as per the annual Wholesale Price Index (WPI) for preceding year on or before 1st April of every year and notify the same on the 1st day of April every year”

It is seen that applicability of Para 16 is appropriate only in the cases where there is revision of prices. However, there is no revision involved in fixing the ceiling price of product that has become scheduled drug for the first time. The impact of WPI should be passed on to the consumers only where the product is already under price control and after completion of one year the WPI for that year is to be taken into consideration for fixation of ceiling price of the product during the ensuing year. Since it is a case of fixation of price of a formulation that has become scheduled for the first time, the concept of applicability of WPI does not seem to be correct. In this connection Para 9(5) reads as under:

“The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six months of notification of revision in the first schedule”

In this case, there is no ceiling price of the product on 1.4.2016. Ceiling price is fixed for the first time on 12.4.2016. So, when there is no ceiling price on 1.4.2016, there cannot be any revision of ceiling price due to WPI. Hence, applying WPI without the ceiling price having been fixed is not in accordance with the provisions of DPCO.

In view of the above, NPPA should fix the ceiling price of the product taking into account the data available for the month ending immediately before six months of the Notification of revision in the first schedule i.e. 10.03.2016 in the instant case in terms of Para 9(5) of the DPCO, 2013. NPPA has erred in applying WPI in this case where it is not applicable.

5. **Government Decision:**

NPPA is hereby directed to re-fix and re-notify the price of the products of the petitioner company under Para 4, by taking the correct data, taking into account Para 9(5) of DPCO, 2013, and without applying WPI change in ascertaining the ceiling price. The same principles should be applied to all other such cases also by NPPA.

In view of the above, the present review petition stands disposed off.

Issued on this date, the 6th day of October, 2016.

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

To

1. **M/s. Alkem Laboratories Ltd.**
Alkem House, Senapati Bapat Marg,
Lower Parel, Mumbai-400 013.
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**