

No. 31015/42/2016-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 "Xone 1 gm (Cetrixone 1 gm Injection)" 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 07.06.2016
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 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. No.1686(E) dated 09.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Xone 1 gm (Cetrixone 1 gm Injection).

2. The petitioner has contended as under:

- I. 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 9th May and intimated NPPA and the State FDAs accordingly.**
- II. Revision of the ceiling price of Xone 1gm 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 clause 4(xi) of the National Pharmaceutical Pricing Policy, 2012 (NPPP-2012) issued on 07.12.2012.
- III. On a proper reading of the DPCO read with the NPPP-2012 it is apparent that mere revision of the NLEM need not result in the re-fixation of ceiling price, but such re-fixation may be undertaken only if there is a consequent change in the "market structure" of a particular formulation based on the revision of the NLEM.
- IV. Under DPCO, a ceiling price calculation is based on the simple averaging of the market prices of different brands of medicines having a market share of 1% and above, based on the Moving Annual Turnover (MAT). Over a period of time, these market shares (based on MAT values of different brands) undergo a change – change in the "market structure" of a medicine. This would be due to new brands entering the market and / or some of the existing brands exiting the

market and / or the inter-se changes in the market shares (collectively referred herein as "market competition"), thereby necessitating a revision in the existing ceiling prices.

- V. When the NLEM is updated / revised (leading to updation / revision of the Schedule-I of DPCO-2013) some of the brands may get reclassified into different therapeutic groups / sub-groups, thereby changing the "market structure" of certain medicines, and thereby necessitating revision in the ceiling prices of such medicines. However, in the present case, the revision of the NLEM has not changed the market structure in respect of the subject formulation. In the circumstances, the revision purported to be made vide the impugned notification is contrary to the provisions of the DPCO.
- VI. Without prejudice to the aforesaid, they further submitted that in terms of paragraph 18 of the DPCO, the 'revision' of ceiling prices in view of the revision of the NLEM has no correlation with the existing ceiling price. Unlike the 'revision' of ceiling price under paragraph 16, which is the upward or downward revision of the existing ceiling price based on the movement of the WPI, the 'revision' under Paragraph 18 is actually a 're-fixation' of ceiling price under paragraph 4. It is submitted that once an exercise is conducted under paragraph 4, the question of applying any effect of the WPI change cannot arise. In revising the ceiling price of the subject formulation, the NPPA has also 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.
- VII. 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 revising the ceiling price.
- VIII. Without prejudice to what is stated above, while going through the working sheet uploaded by the NPPA, they identified that there for Alkem there appears four brands appearing in working as follows:

Product	Company	S.No in working Sheet
CEFAST 1000 MG INJECTION	Alkem	5
CEFTISURE 1000 MG INJECTION	Alkem	6
XONE HOSPITAL PACK 1000 MG INJECTION	Alkem	7
XONE 1000 MG INJECTION	Alkem	8

- IX. They **would like to state that the brand appearing in serial no 7 is incorrect**, they are not selling any such product, and this has been wrongly included. They requested Government to ask NPPA to kindly drop this product from the working

sheet and order NPPA to withdraw the 're-fixation' of the ceiling price in respect of the subject formulation.

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 55.44 per pack vide S.O. 2235(E) dated 22.7.2013 and the same was revised to Rs. 58.94, Rs. 61.21 & Rs. 59.55 per pack vide S. O. 1156(E), S. O. 619(E) & S. O. 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016.
- (ii) NLEM 2011 is substituted by NLEM 2015 therefore, NPPA has fixed ceiling price of Rs. 47.95 per pack under para 18 of DPCO, 2013.
- (iii) Company's representation is under examination.

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. There is no product named "Xone Hospital Pack" which is appearing in the working sheet. Hence, the company request NPPA to remove the same from their working sheet.
- III. In case of Trusten 1 gm of Zuventus, NPPA has not considered the actual PTR as per AWAC data base. Hence, the company request NPPA to consider actual PTR in the working of ceiling price.

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 matter at Point No.II above is under examination based on the representation made by M/s Alkem Laboratories Ltd. Regarding point III, the same may be examined by NPPA.

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 I on the 10th March, 2016, incorporating NLEM 2015, these products continued to be in Schedule I.

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 I. NPPA is fully within its powers to revise the ceiling prices. The contention of the petition has no justification and may be rejected.

As regards, company's representation that there is no product named “Xone Hospital Pack” which is appearing in the working sheet, the same is under examination at NPPA. Regarding Trusten 1 gm of Zuventus, not been considered the actual PTR as per AWAC data base, the same may be examined by NPPA.

5. Government Decision:

In view of the above, the petition of the company with regard to quashing/ setting aside of the NPPA SO No.1686(E) dated 9.5.2016 stands rejected.

However, NPPA is directed to examine any relevant data / information being furnished by the petitioner company on merit and the ceiling price of the formulation be refixed within a period of one month from the date of issue of the this Order.

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

Issued on this date, the 14th day of September, 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**