

**No. 31015/59/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

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

Subject: Review application of M/s Alkem Laboratories Limited against price fixation of "Xone 1 gm (Cefriaxone 1 gm Injection)" vide NPPA order No. S.O. 1271(E), dated 21.04.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 12.05.2017
2) NPPA notification under review S.O. 1271(E), dated 21.04.2017
3) Record Note of discussions held in the personal hearing held in the matter on 26.09.2017.**

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 Limited (hereinafter called the petitioner) against notification S.O. No.1271(E), dated 21.04.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Xone 1 gm (Cefriaxone 1 gm Injection).

2. The petitioner has contended as under:-

- I. Company submitted that the 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 13.
- II. In the working sheet of ceiling price calculation NPPA has considered Company levelwise MAT while in DPCO 13 there is no such provision. The product became a controlled formulation for the first time in May 2013, when DPCO 2013 was notified. Subsequent to the same the ceiling price of the product was fixed for the first time as Rs 55.44 vide S.O. on 2235 (E) dt 22.07.2013. Further the ceiling were notified under para 16 for revision in WPI vide S.O 1156 dt 28.04.2014 as Rs 58.94, S.O. 619(E) dt 26.02.2015 as 61.21, S.O. 644(E) dt 02.03.2016 as 59.55.
- III. The company further stated that subsequent to the S.O. 644, NPPA recalculated and renotified the Ceiling Price based on para 18, vide S.O. 1686 dt 09.05.2016 as 47.95. Hence the ceiling price have been worked out by NPPA under para 18 in S.O. 2235 on 22.07.2013 and S.O.1686 on 09.05.2016.
- IV. Company have compared the working sheet of above two notifications, and submitted that in the working sheet for S.O. 2235 dated 22.07.2013, there were

altogether 4 packs of Ceftriaxone shown in the name of our company viz Alkem, as per details given below:

Sr. No.	Brands	Pack Description
1	CEFAST	CEFAST INJ DRY VIAL 1 G
2	CEFTISURE	CEFTISURE INJ DRY VIAL 1 G
3	TRAXOL	TRAXOL INJECTION DRY VIAL 1 G
4	XONE	XONE INJ DRY VIAL 1 G

V. Similarly in the working sheet for S.O. 1686 dated 09.05.2016, there were 5 packs and those are given below:-

Sr. No	BRAND	Pack Description	Company
1	CEFAST	CEFAST 1000 MG INJECTION 1	ALKEM
2	CEFTISURE	CEFTISURE 1000 MG INJECTION 2 ML	ALKEM
3	TRAXOL	TRAXOL 1000 MG INJECTION 10 ML	CACHET
4	XONE	XONE 1000 MG INJECTION 5 ML	ALKEM
5	XONE	XONE HOSPITAL PACK 1000 MG INJECTION 1	ALKEM

VI. Company stated that in the initial working sheet there was no such pack as Xone Hospital Pack, and hence any new addition in working needs to be checked if the pack is introduced or marketed by the company.

VII. Company further mentioned that NPPA have never confirmed with company whether Company is manufacturing any such pack as Xone Hospital Pack. In spite of the same, Company had informed NPPA vide our letter no. ALL/PJP/192 dated 13.04.2017 & dated 11.04.2017 that they have discontinued the pack of Cefast & Ceftisure on Jan 2013 and Xone Hospital Pack on May 2012. Company has even submitted a Chartered Accountant certificate for the same. Company noted that in the working sheet, NPPA has removed Cefast and Ceftisure while they retained Xone HP pack.

VIII. In view of above, company requested this Department to direct NPPA to refix ceiling price based on, only those pack which have market share of more than 1% and remove the pack Xone 1 gm Hospital Pack from the working explicitly.

Comments of NPPA:

- I. Ceiling price of Ceftriaxone 1 gm injection (Xone 1gm Injection) was notified as Rs.48.74 per pack and the same was revised to Rs.46.74 per pack vide S.O. 2058 (E) dated 30.06.2017 under para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.
- II. The company has stated that correct methodology was not followed (as per para 4&18 of DPCO, 2013) in arriving at the ceiling price of Ceftriaxone 1 gm injection (Xone 1gm Injection). The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	<p>The company has stated that NPPA has considered company wise MAT while fixing ceiling price, but in DPCO, 2013 there is no such provision. In support of their claim company referred OM F.No. 31026/31/2016-P.I.I (Pt-III). Company re-iterated that while fixing the ceiling prices of scheduled formulations, MAT & PTR of only those medicines/formulations shall be considered which are having 1% or more market share.</p> <p>Company again stated that NPPA fixed ceiling price for the first time as Rs. 55.44 vide S.O. 2235(E) dated 22.07.2013. Further, the ceiling price were notified under para 16 for revision in WPI vide S.O. 1156 dated 28.04.2014 as Rs.58.94, S.O. 619(E) dated 26.02.2015 as Rs.61.21, S.O. 644(E) dated 02.03.2016 as Rs.59.55. Company compared the working sheet for S.O. 2235 (E) dated 22.07.2013 to S.O. 1686 (E) dated 09.05.2016. Company observed that in the working sheet pertaining to S.O. 2235 (E) dated 22.07.2013, NPPA has not considered their Pack "Xone Hospital Pack" while in the working sheet pertaining to S.O. 1686 (E) dated 09.05.2016, NPPA considered the same without confirming from the company. Company has also stated that they have informed NPPA about the discontinuation of their pack Cefast and Ceftisure on Jan, 2013 and Xone Hospital pack on May, 2012. As per company claim, they have submitted a Chartered Accountant certificate for the same. Company objection is that NPPA has removed Cefast and</p>	<p>NPPA fixed the ceiling price Rs. 48.74/pack for Ceftriaxone powder for injection-1gm vide S.O. 1271 (E) dated 21.04.2017. NPPA issued notification 1271 (E) dated 21.08.2017 in compliance of the direction given in line with review order no. 31015/42/2016-P.I.-I dated 14.09.2016. The detail of particular hospital pack was present on the website of the company, although, the company has stated that the product is not there. The other two products of the company were not present on the website. Therefore, NPPA considered particular hospital pack in calculating the ceiling price of subject formulation.</p> <p>The inclusion of company wise MAT having 1% or more market share is according to the decision of calculating ceiling price based on the least of the 3 alternatives by the Authority in its 27th meeting held on 29.03.2016.</p>

Ceftisure from working sheet but retained Xone Hospital pack.	
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3. During the personal hearing, the company representatives requested to implement the OM No.31026/31/2016-PI.I.(Pt-III), issued by DoP dated 20.4.2017 and revise the ceiling price of Ceftriaxone 1gm injection.

4. NPPA representatives did not make any additional submissions.

5. Examination:

On examination, it is found that NPPA has erred in calculating ceiling price as per para 4 of DPCO, 2013. It clearly mentions that the medicines having PTR and MAT value of more than 1% market share are to be taken for calculation. In the instant case, the principles applied by NPPA go beyond what is mentioned in DPCO. Hence, NPPA may be directed to refix the ceiling price in accordance with the provisions of DPCO. 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>
Xone 1 gm (Cefriaxone 1 gm Injection)	15	8

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 regards the contention of the petitioner company about discontinued packs Cefast, Ceftisure and Xone Hospital pack, it is seen that NPPA has already not considered PTRs of two packs, viz. Cefast and Ceftisure. However, NPPA considered the PTR of Xone Hospital pack on the ground that it was available on the website of the company. Company has submitted CA certificate in support of its claim about discontinuation of Xone Hospital Pack. On going through the calculation sheet, it is seen that market share of this product is only 0.10%, which is being directed to exclude the PTR (of Xone Hospital Pack) while calculating ceiling price as per para 4 of DPCO, 2013.

4. Government Decision:

“NPPA is directed to refix the ceiling prices of the formulation Xone 1 gm (Cefriaxone 1 gm Injection) by considering only those medicines / formulations having MAT value of more than 1% market share, strictly in accordance with DPCO, 2013.”

Issued on this date, the 10th day of October, 2017.

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

To

1. M/s. Alkem Laboratories Limited
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