

**No. 31015/48/2017-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 Sun Pharmaceutical Industries Limited against price fixation of "Gemcitabine 200mg Injection" vide NPPA order No. S.O. 443(E), dated 14.02.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application dated 10.03.2017  
2) NPPA notification under review S.O. 443(E), dated 14.02.2017  
3) Record Note of discussions held in the personal hearing held in the matter on 10.10.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Limited (hereinafter called the petitioner) against notification S.O. No.443(E), dated 14.02.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Gemcitabine 200mg Injection.

2. The petitioner has contended as under:-

I. Company submitted that company is aggrieved by the said notification as the price of their product XTROZ 200 mg Injection was incorrectly captured in ceiling price calculation; and hence the revision in ceiling price is improper. Company sought a review of the same under paragraph 31 of DPCO 2013 on the following grounds:

(i) The draft working sheet of 15 formulations including captioned formulations was displayed on NPPA website on 23.11.2016. Company's 2 products were shown in the draft working sheet, viz. XTROZ 200 MG INJECTION<sup>1</sup>, GEMTAZ 200 MG INJECTION 1. Price to Retailer (PTR) of pack XTROZ 200 MG INJECTION 1 was captured incorrectly as Rs. 790 per pack in the ceiling price calculation, when the August 2015 month PTR was Rs. 1132.91. Company submitted its representation dated 02.12.2016 along with necessary documents within 10 working days of draft working sheet presentation on NPPA website.

(ii) Company had received a letter dated 13.12.2016 (Ref: F. No. 7(84)/2016/DP/NPPA/Div. II) from NPPA for submitting the sample for the month of August 2015, within 7 days (by 20.12.2016), which company had duly submitted through their letter dated 16.12.2016.

(iii) NPPA has notified the ceiling price of captioned formulations via S.O. 443(E) dated 14.02.2017 without considering company's representation and submissions.

- II. In view of above, company requested this Department to issue necessary directives to NPPA to re-notify the ceiling price of the said formulation.

3. **Comments of NPPA:**

(i) Ceiling price Rs. 1069.33/pack is notified for Gemcitabine 200 mg injection vide S.O. 443 (E) dated 14.02.2017 & the same was revised to Rs. 1045.77/pack vide S.O. 2058 (E) dated 30.06.2017 as per Para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

(ii) The company has stated that correct methodology was not followed in arriving at the ceiling price of Gemcitabine 200 mg 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.	Company has stated their two products viz. Xtroz 200 mg injection, and Gemtaz 200 mg was shown in draft working sheet. NPPA considered PTR Rs.790 for Xtroz 200 mg injection against the actual PTR Rs. 1132.91 for the month of August, 2015. Company also pointed out that they have submitted representation vide letter dated 02.12.2016 along with necessary documents within 10 working days of draft working sheet.	NPPA examined the representation and documents submitted by the company. The company has not submitted all the requisite documents within 10 working days in line with the requirement as per OM no. 8(34)/2014/Div.II/NPPA dated 10.10.2016 & OM F.no.20(1)/2014/Div.III/NPPA dated 01.02.2017. In addition, IPDMS compliance was 68% as on 07.02.2017. Therefore, the same was not considered by the authority.
2.	Company received a letter F.no. 7(84)/2016/DP/NPPA/Div.II dated 13.12.2016 for submitting the sample for the month of August, 2015, within 7 days (by 20.12.2016). Company submitted the same vide letter dated 16.12.2016.	Since the company has not submitted all the requisite documents within 10 working days from the uploading of draft working sheet in NPPA website, the same was not considered.
3.	NPPA notified the ceiling price for Gemcitabine 200 mg injection without considering their representation.	

(iii). Company has not challenged in any Court in respect of ceiling price fixation for Gemcitabine 200 mg injection S.O. 443 (E) dated 14.02.2017.

4. During the personal hearing, the representatives of the company further submitted that though the company have filed Representation and Review Application

for incorrect PTR considered in Ceiling Price Calculation of their Product Xtroz Injection 200mg, since it is having less than 1% market share the company representative requested the authority that product viz. Xtroz Injection 200mg should be excluded from the Ceiling Price Calculation.

**5. Examination:**

In the instant case, the company claimed that correct PTR of their formulation XTROZ 200 MG INJECTION 1 was not considered by NPPA. The company stated that NPPA has considered the PTR of XTROZ 200 MG INJECTION 1 as Rs.790.00 against the actual PTR of Rs.1132.91 for the month of August, 2015. The company, in support of its claim, submitted a representation to NPPA on 2.12.2016. However, on going through the calculation sheet, it is found that the market share XTROZ 200 MG INJECTION 1 of M/s Sun Pharmaceuticals Industries Limited, for which company is raising PTR issue, is less than 1%, (it is only 0.40%), and should not be considered while arriving at the ceiling price under para 4 of DPCO, 2013. NPPA has considered the PTR based on company wise market share of MAT value, whereas DPCO does not recognize a company for average PTR but only medicines/formulations. In view of this, NPPA may be directed to re-fix and re-notify the ceiling price of formulation **Gemcitabine 200mg Injection** by not considering the MAT value of XTROZ 200 MG INJECTION 1 having less than 1% market share.

**6. Government Decision:**

**“NPPA is hereby directed to re-fix and re-notify the ceiling price of formulation Gemcitabine 200mg Injection by not considering the MAT value of XTROZ 200 MG INJECTION 1 having less than 1% market share.”**

Issued on this date, the 1<sup>st</sup> day of December, 2017.

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

To

1. M/s. Sun Pharmaceutical Industries Limited,  
8-C, 8<sup>th</sup> Floor, Hansalaya Building,  
15, Barakhamba Road, Connaught Place,  
New Delhi-110 001.
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