

No. 31015/96/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

.....

B Wing, Janpath Bhawan,
New Delhi 110 001

Subject: Review application of M/s J.B. Chemicals & Pharmaceuticals Limited against price fixation of Ranitidine Injection - 25 mg/ml vide NPPA order No. S.O. 3431(E), dated 10.11.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 18.11.2016
2) NPPA notification under review S.O. No. 3431(E) dated 10.11.2016
3) Record Note of discussions held in the personal hearing held in the matter on 27.12.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s J.B. Chemicals & Pharmaceuticals Limited (hereinafter called the petitioner) against notification S.O. No.3431(E) dated 10.11.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Ranitidine Injection - 25 mg/ml.

2. The petitioner has contended as under:
 - I. National Pharmaceutical Pricing Authority (hereinafter referred to as NPPA) under the Department of Pharmaceutical, Ministry of Chemicals and Fertilizers, Government of India issued a notification no S.O. 3431 (E) dated 10th November, 2016, fixing prices of thirty four (34) Scheduled formulations inter alia including "RANTAC INJECTION 5 x 2ML" each 1ml containing RANITIDINE INJECTION - 25MG/ML at Sr.No.16, after giving effect of reduction in Wholesale Price Index (WPI) for the calendar year January to December, 2015.

- II. AND WHEREAS ceiling price notified for formulation RANITIDINE INJECTION - 25MG/ML, as shared in NPPA's worksheet for S.O. 3431 (E) dated 10TH October, 2016, fails to mention the aforesaid formulation pack namely "RANTAC INJECTION 5 x 2ML". AND WHEREAS, JBCPL is a major manufacturer of the scheduled formulation RANITIDINE INJECTION - 25MG/ML having Moving Annual Turnover (MAT) of INR.8.8 Crores which would be over 30% of the market as NPPA worksheet only mentions total MAT for August, 2015 at INR. 16.18 Crores.
- III. Company further submitted that:-
- a. it need to be appreciated that NPPA has failed to accurate calculate the ceiling price of RANITIDINE INJECTION - 25MG/ML.
 - b. There was no rational for not considering our formulation "RANTAC INJECTION 5 x 2ML" each 1ml containing RANITIDINE INJECTION - 25MG/ML especially when JBCPL covers over 30% MAT value.
 - c. The ceiling price "RANITIDINE INJECTION - 25MG/ML" is not correctly calculated considering all manufacturers over 1% market share and the consequently notified price is not as per the provisions of Para 4 of DPCO, 2013.
- IV. Having been aggrieved by the fact that the ceiling price of the captioned formulation RANITIDINE INJECTION - 25MG/ML was not correctly notified under S.O. 3431 (E) dated 10th November, 2016 due to exclusion of our formulation with over 30% market share;
- V. JBCPL files this Review Petition under Para 31 of the Drugs (Prices Control) Order, 2013 against S.O. No. 3431 (E) dated 10th November, 2016 and **request to pass a speaking order in the matter.**

VI. Under the circumstances, The Applicant hereto MOST HUMBLY AND RESPECTFULLY PRAY as under:

- a) To consider and conclude that Ceiling Price of “RANITIDINE INJECTION - 25MG/ML” as notified vide S.O 3431(E) dated 10th November, 2016 is incorrect and needs to consider their formulations in its calculation.
- b) Pass a speaking order in respect hereof.
- c) Any other order in interest of this manufacturer.

COMMENTS OF NPPA

(i) NPPA has fixed the ceiling price Rs. 1.43 for **Ranitidine 25mg/ml Injection** vide S.O. 1157(E) dated 28.4.2014 and the same was revised to Rs. 1.52, Rs. 1.58, Rs. 1.55, 1.61 & Rs. 1.57 per ml vide S.O. 2095(E), 619(E), 837(E) & 644(E) dated 20.8.2014, 26.02.2015, 25.3.2015 02.3.2016 respectively under NLEM 2011 of DPCO 2013.

(ii) NPPA fixed the ceiling price of Rs. 1.48/ml for **Ranitidine 25mg/ml Injection** vide S. O. 3431(E) dated 10.11.2016 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013 under NLEM 2015, based on the data provided by Pharmatrac for the month of August 2015.

(iii) DOP vide letter no. F. No. 31015/44/2016-PI.I dated 11.7.2016 gave the following directions: “*NPPA to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from*

*the affected pharmaceuticals firms. Only after taking into account the comments or any additional data thus received within the given time period, the NPPA shall finalize the Ceiling and the Retail Prices. This issues with the approval of Hon'ble Minister (Chemicals & Fertilizers)". Accordingly, NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was displayed on the website of NPPA for 10 clear working days. **M/s J. B. Chemicals & Pharmaceuticals Limited did not make any representation against the proposed ceiling price uploaded on NPPA's website.***

3. The company was given personal hearing on 27.12.2016 and during the hearing, the representatives of the company submitted that the work sheet for SO 3413(E), dated 10.11.2016 was incorrect due to the following reasons –

- (i) JBCPL is a major manufacturer having MAT of over Rs.11.00 crores constituting nearly 57% of the market share and thus, the product of the company i.e. Rantac Injection 50 mg/2ml should be considered,
- (ii) Certain other formulations namely R-loc, Histac and Peploc should also be considered as their pack sizes are also 50 mg/2ml.
- (iii) Zinetac and Ranitin must not be considered as their strength is different from the scheduled formulation Ranitidine 25 mg/ml.

In support of the above mentioned claims, the company has submitted a certificate from Pharmatrac software by AWACS-AIOCD.

NPPA representatives submitted that based on the DoP letter No.31015/44/2016-PI.I, dated 11.7.2016, NPPA had uploaded the draft working sheet atleast 10 working days prior to issue of ceiling price notification, with a view to obtain representation from the aggrieved companies, which M/s JBCPL has not given. Regarding wrong/non-inclusion of certain SKUs in the ceiling price calculation of **Ranitidine 25mg/ml Injection**, NPPA representative further stated that the same may be verified on receipt of data/information from the aggrieved company.

4. **Examination:**

As per instructions of DoP vide letter No.F.No.31015/44/2016-PI.I, dated 11.7.2016 NPPA was directed to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceuticals firms. Only after taking into account the comments or any additional data thus received within the given time period, the NPPA shall finalize the Ceiling and the Retail Prices. Accordingly, NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was displayed on the website of NPPA for 10 clear working days. **M/s J. B. Chemicals & Pharmaceuticals Limited did not make any representation against the proposed ceiling price uploaded on NPPA's website. The company admitted that it did not submit an objection to the draft ceiling price as the draft was released during the holiday period and was missed out by the company.** Although the company did not avail the opportunity, however, the company filed the review application under para 31

of DPCO,2013, to get its grievance settled. It is observed that there is a merit in the grievance of the petitioner company that NPPA missed out certain data/information while fixing the ceiling price of the formulation Ranitidine 25mg/ml Injection. Therefore, Hearing Authority is of the opinion that NPPA may be directed to examine the relevant document/information submitted by the petitioner company and to re-fix the ceiling price of Ranitidine 25mg/ml on merit.

6. **Decision of the Government:**

NPPA is hereby directed to examine all the relevant documents/information furnished by the petitioner company and to re-fix the ceiling price of **Ranitidine 25mg/ml** on merit, within 30 days of this Order and to send the compliance report to the Department.

Issued on this date, the 4th day of May, 2017.

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

To

1. **M/s. J.B. Chemicals & Pharmaceuticals Limited**
“NEELAM CENTRE”, ‘B’ Wing, 4th Floor, Hind Cycle Road,
WORLI, Mumbai-400 030.
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**