

No. 31015/50/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A- Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Two Review applications of M/s J.B. Chemicals & Pharmaceuticals Ltd. against price fixation of “Ranitidine Injection 25Mg/ml and Ranitidine Syrup 75mg/5ml.” vide NPPA order No. S.O. 1039(E), dated 01.04.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref:

- 1) Two Review applications dated 20.04.2017
- 2) NPPA notification under review S.O. 1039(E), dated 01.04.2017
- 3) Record Note of discussions held in the personal hearing held in the matter on 11.07.2017.

1. These are two petitions under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s J.B. Chemicals & Pharmaceuticals Ltd. (hereinafter called the petitioner) against notification S.O. No.1039(E), dated 01.04.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Ranitidine Injection 25Mg/ml and Ranitidine Syrup 75mg/5ml.

2. The petitioner has contended as under:-

I. National Pharmaceutical Pricing Authority (NPPA) issued notification no S.O. 1039(E) dated 01st April, 2017 revising prices by WPI of calendar year 2016 of Ranitidine Injection 5x2 ml Sr. No. 558 and Ranitidine Oral Liquid at Sr. No. 559 under the provisions of Para 4 and 16 of Drugs (Prices Control) Order (DPCO), 2013.

II. **In respect of Ranitidine Injection 25Mg/5ml**

(i) AND WHEREAS, the base ceiling price for Ranitidine injection 5x2 ml inaccurately notified vide S.O. 3431(E) Dated 10th Nov, 2016 wherein NPPA had erred by considering the incorrect ceiling price of their formulation

(ii) AND whereas, JBCPL is a major manufacturer of the scheduled formulation RANITIDINE INJECTION-25MG/5ML having moving Annual Turnover (MAT) of Rs.8.8 crores which would be over 30% of the market as NPPA worksheet only mentioned total MAT for August,2015 at Rs.16.18 crores.

Under the circumstances:

- (a) It needs to be appreciated that NPPA has failed to accurately calculate the ceiling price of RANITIDINE INJECTION-25MG/5ML.
- (b) NPPA is now compounding the same error by revising the ceiling price to give effect of WPI of the calendar year 2016(1.97186%).
- (c) NPPA must first either correct the base ceiling price in accordance with Para 4 of DPCO 2013 or wait for Review Petition Order.

III. In respect of Ranitidine Syrup 75mg/5ml

- (i) AND WHEREAS, the base ceiling price for Ranitidine Oral Liquid was inaccurately notified vide 1560(E) dated 27th April, 2016 wherein NPPA had erred by considering the incorrect ceiling price of their formulation and the matter is currently subjudice at Bombay High Court.

Under the circumstances:

- (a) NPPA had erred in accurately notifying the ceiling price of Ranitidine Oral Liquid as per the provision of Para 4 vide S.O.No.1560(E) dated 27th April 2016.
- (b) NPPA is now compounding the same error by revising the ceiling price to give effect of WPI of the calendar year 2016(1.97186%).
- (c) NPPA must first either correct the base ceiling price in accordance with Para 4 of DPCO 2013 or wait for the subjudice Court case to be resolved.

IV. In view of above, applicant prayed as under:-

- a. To consider and conclude that ceiling price of **RANITIDINE INJECTION-25MF/5ML** as notified vide. S.O. 3431(E) dated 10th November, 2016 is incorrect and needs to consider their formulation in its calculation.
- b. To consider and conclude that NPPA had erred in pricing of their formulation **Ranitidine Oral Liquid** under Notification no. S.O. 1039(E) dated 01st April, 2017.
- c. To consider and conclude that NPPA must revise the ceiling price of the **Ranitidine Oral Liquid** in accordance with provisions of Para 4 of DPCO, 2013 considering all SKUs having market share more than 1%

Comments of NPPA:

- I. Ceiling price of **Ranitidine Injection 25mg/ml** was notified as Rs. 1.48/ml vide S.O. 3431(E) dated 10.11.2016 and revised to Rs. 1.51/ml vide S.O. 1039(E) dated 01.04.2017 and ceiling price of **Ranitidine Syrup 75 mg/5ml** was notified

as Rs. 0.54/ml vide S.O. 1560(E) dated 27.04.2016 and revised to Rs. 0.55/ml vide S.O. 1039(E) dated 01.04.2017 as per para 4, 10, 11, 14, 16, 17 & 18 under DPCO 2013.

- II. The company stated that correct methodology was not followed in arriving at the ceiling price for **Ranitidine Injection 25mg/ml and Ranitidine Syrup 75 mg/5ml**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013 and as per the decisions of 27th Authority meeting held on 29.3.2016. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Ranitidine Injection 25mg/ml :- Base ceiling price for Ranitidine Injection 25/ ml inaccurately notified vide S.O. 3431(E) dated 10.11.2016 by considering the incorrect ceiling price of our formulation.	The Authority notified the ceiling price of Ranitidine Injection 25mg/ml in terms of the decision taken in its 38th meeting held on 09.11.2016 vide S.O. No. 3431(E) dated 10.11.2016.
2.	NPPA vide notification no. SO 1039(E) dated 01.04.2017 revised the prices by WPI of calendar year 2016 of Ranitidine Injection 5*2ml under the provisions of para 4 and 16 of DPCO, 2013.	The S.O. 1039(E) dated 01.04.2017 was issued to give the effect of WPI applicable from 01.04.2017 only. NPPA considered the data provided by AIOCD-AWACS for month of August 2015. Review order no. 31015/98/2016-PI.I dated 04.05.2017 issued by DOP for re-fixing the ceiling price of Ranitidine Injection 25mg/ml is to be placed before the Authority in the next meeting for implementation.
3.	M/s JB CPL is a major manufacturer of scheduled formulation, Ranitidine Injection 25mg/ml having Moving Annual Turnover (MAT) of INR 8.8 crores while in calculation sheet, NPPA mentioned total MAT for August' 2015 at INR at Rs. 16.18 crores.	NPPA considered the data provided by AIOCD-AWACS for month of August 2015. NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. M/s J. B. Chemicals & Pharmaceuticals Ltd. <u>did not make any representation against the proposed ceiling price uploaded on NPPA's website.</u>
4.	NPPA has failed to accurately calculating the ceiling price of Ranitidine Injection 25mg/5ml.	NPPA fixed the ceiling price based on the data provided by AIOCD-AWACS for month of August 2015.
5.	NPPA is now compounding the same error by revising the ceiling price to effect of WPI of calendar year 2016 (1.97186%).	The S.O. 1039(E) dated 01.04.2017 was issued to give the effect of WPI applicable from 01.04.2017 only.

6.	<p>Ranitidine Syrup 75 mg/5ml :-</p> <p>1. NPPA vide SO no 1039(E) dated 01.04.2017 revised the prices by WPI of calendar year 2016 of Ranitidine oral liquid under the provision of para 4 and 16 of DPCO, 2013.</p> <p>2. The base ceiling price for Ranitidine oral liquid inaccurately notified vide SO 1560(E) dated 27.04.2016 where in NPPA had error by considering the incorrect ceiling price of our formulation and the matter is current subjudice at Bombay High Court.</p> <p>3. NPPA is now compounding the same error by revising the ceiling price to effect of WPI of calendar year 2016 (1.97186%).</p> <p>4. NPPA must first either correct the base ceiling price in accordance with para 4 of DPCO, 2013 or wait for the subjudice Court Case to be resolved.</p>	<p>The S.O. 1039(E) dated 01.04.2017 was issued to give the effect of WPI applicable from 01.04.2017 only. NPPA considered the data provided by AIOCD-AWACS for month of August 2015. Review order issued by DOP for re-fixing the ceiling price of Ranitidine Syrup 75mg/5ml is under consideration.</p> <p>NPPA has fixed ceiling price Rs. 0.54/ml vide SO no. 1560(E) dated 27.04.2016 in terms of the decision taken in 29th Authority Meeting held on 27/04/2016 as per the provisions of DPCO, 2013.</p> <p>The S.O. 1039(E) dated 01.04.2017 was issued to give the effect of WPI applicable from 01.04.2017 only.</p>
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III. Company has challenged SO no. 1560(E) dated 27.04.2016 in Bombay High Court in respect of Ranitidine oral liquid 75 mg/5ml, decision is awaited.

3. During the personal hearing, the representatives of the company, in addition to their earlier submissions, stated that –

In respect of Ranitidine Injection 25Mg/5ml

- NPPA issued notification no. S.O. 1039(E) dated 1st April'2017 in respect of Ranitidine Injection 25mg/5ml, under Para 4 for Price Revision as per Annual Wholesale Price Index (WPI) @ 1.97186% increase.
- The ceiling price w.e.f (01.04.2017 with WPI @1.97186%) was erroneously fixed as Rs.1.51/per ml. This was due to the fact that the base price was incorrectly taken.
- Despite having DOP's direction to examine all the relevant documents / information furnished by the company and to re-fix the ceiling price of Ranitidine 25mg/ml on merit within 30 days of the order dated 4th May'2017, NPPA have not revised the ceiling price.
- The above order was in lieu of the Review done with DOP on 27th December'2016 against SO no. 3431 dated 10th Nov'2016.

- The incorrect base price was notified by SO 3431 (E) dated 10th November'2016. The error was due to the fact that NPPA has not included the company's formulation in the price calculation despite having considerably more than market share than the 1% as required under Para 4 of DPCO, 2013.
- NPPA has failed to accurately calculate the ceiling price of RANITIDINE INJECTION – 25MG/ML
- There was no rationale for not considering the company's formulation "RANTAC INJECTION 5 x 2ML" each 1ml containing RANITIDINE INJECTION – 25MG/ML especially when JBCPL covers more than 1% MAT value.
- In support to above statement, Company had provided the AWACS certificate dated 22nd Dec'2016, source AWACS MAT'15, which clearly indicate that "RANTAC INJECTION 5 x 2ML" each 1ml containing RANITIDINE INJECTION – 25MG/ML has MAT value Aug'15 as 116335297, which is more than 1% market share required under Para 4 of DPCO 2013, for considering the product while fixation of the ceiling price of the brand.
- Without prejudice, the company submitted that the data considered for calculation of ceiling price under Para 4 as notified while SO 3431(E) dt. 10th November'2016 is incorrect to the extent that the price per unit of certain Rantac injection 5X2ml was not considered.
- For ready reference, company provided the correct calculations based on the corrected AWACS data.

Price Calculation of Ranitidine Injection 25 mg/5ml								
Company	Pack Description	Unit	PTR	Mat Value	Market share	Qualify (Y/N)	pack size	PTR per m
JB CHEMICALS	RANTAC 50 MG INJECTION 2 ML	2	2.78	116142899	57.03%	Y	2	1.39
ZYDUS CADILA	R-LOC 50 MG INJECTION 2 ML	2	2.60	72665992	35.68%	Y	2	1.30
RANBAXY LABORAT	HISTAC 50 MG INJECTION 2 ML	2	2.77	13044965	6.41%	Y	2	1.39
ZYDUS CADILA	PEPLOC 50 MG INJECTION 2 ML	2	1.91	1289484	0.63%	N	2	
UNICHEM LABORAT	RANX L 50 MG INJECTION 2 ML	2	71.93	365609	0.18%	N	2	
GLAXOSMITHKLINE	RANITIDINE(GLAXO) 50 MG INJECTION 2 ML	2	2.55	71905	0.04%	Y	2	0
ZYDUS CADILA	GERTAC 50 MG INJECTION 2 ML	2	1.91	55337	0.03%	N	2	
					0.00%	Y	2	-
				203636191				
						Sum PTR		4.075
						Average		1.36
						Retailer Margin 16%		0.22
						Ceiling price without Local taxes		1.58
						WPI reduction of -2.71% .w.e.f 1/04/2016		0.04
						Final ceiling price without local taxes		1.53
						WPI reduction of +1.971% .w.e.f 1/04/2017		0.03
						Final ceiling price without local taxes		1.56
So the correct ceiling price should have been Rs.1.56 instead of Rs.1.51 which was notified by NPPA vide SO no. 1039 (E)								

- As can be seen, the correct price of the product works out to Rs 1.56 per ml instead of Rs.1.51 per ml as notified by the SO 1039(E) dated 1st April'2017.
- Thus the company requested to order revision in calculations of ceiling price and subsequently provide the effect of WPI for the calendar year 2017.

In respect of Ranitidine Syrup 75mg/5ml

- NPPA issued notification no. S.O. 1039(E) dated 1st April'2017 in respect of Ranitidine Syrup 75mg/5ml, under Para 4 for Price Revision as per Annual Wholesale Price Index (WPI) @ 1.97186% increase.
- The ceiling price w.e.f (01.04.2017 with WPI @1.97186%) was erroneously fixed as Rs.0.55/per ml. This was due to the fact that the base price was incorrectly taken.
- The incorrect base price was notified by SO 1561(E) dated 27th April'2016. The error was due to the fact that the following product prices were not considered while calculating the ceiling price of Ranitidine Syrup 75ml /5ml.

Composition	Pack	Brand	Company	Strength	Pack size	PTR	Mat %	Price per ml
Ranitidine	Rantac Syrup 30 ml	Rantac	JB.Chemicals	75mg/5ml	30 ml	29.25	2.03%	0.98
Ranitidine	Aciloc Liquid 15mg 100/ml	Aciloc	Cadila	15mg/ml	100 ml	62.40	8.15%	0.62

- In support to above statement, Company provided the AWACS certificate dated 18th Jan'2017, source AWACS MAT'15 which clearly indicated that above mentioned brand were active as per the AWACS MAT Aug'15 data and the same were not considered while calculating the ceiling price.
- Without prejudice, the company submitted that the data considered for calculation of ceiling price under Para 4 as notified while SO 1561(E) dt. 27th April'2016 is incorrect to the extent of the price per unit of certain formulations were not considered.
- For ready reference, company provided correct calculations based on the corrected AWACS data.

Price Calculation of Ranitidine Oral Liquid 75ml/5ml									
Company	SKU	Strength	Pack	PTR	Mat Value	Market sh	Brand MS	pack size	PTR per ml
Cadila Pharma	Aciloc Liquid 15mg 100 /ml	15MG/ml	100 ml	62.4	0.8743	8.15%	8.15%	100	0.62
J.B.Chemicals	Rantac 75mg syrup 100 /ml	75 mg / 5 ml	100 ml	53.5	7.96569	74.30%	74.30%	100	0.54
J.B.Chemicals	rantac syrup 30 ml	75 ml / 5 ml	30 ml	29.25	0.217504	2.03%	2.03%	30	0.98
Mankind	Ranidom PD 75mg syrup 100 ml	75 ml / 5 ml	100 ml	41.6	1.198866	11.18%	11.18%	100	0.42
Ajanta	Peptiran 75 mg syrup 100 ml	75 ml / 5 ml	100 ml	44.83	0.464873	4.34%	4.34%	100	0.45
					10.72123				
							Sum PTR		2.9983
							Average		0.60
							Retailer Margin 16%		0.10
							Ceiling price without Local taxes		0.70
							WPI reduction of -2.71% .w.e.f 1/04/2016		0.02
							Final ceiling price without local taxes		0.68
							WPI reduction of +1.971% .w.e.f 1/04/2017		0.01
							Final ceiling price without local taxes		0.69
So the correct ceiling price should have been Rs.0.69 instead of Rs.0.55 which was notified by NPPA vide SO no. 1039 (E)									

- As can be seen, the correct price of the product works out to Rs 0.69 per ml instead of Rs. 0.55 per ml as notified by the SO 1039 dated 1st April'2017.
- Thus the company requested to order revision in calculations of ceiling price and subsequently provide the effect of WPI for the calendar year 2017.

4. The submission of NPPA representative is as follows:

- a. Ranitidine Injection 25mg/ml: NPPA has complied the review order no. 31015/96/2016-PI.I dated 04.05.2017 with respect to the subject formulation vide SO. 2401(E) dated 28.7.2017 based on the OM dated 13.4.2017 issued by NPPA regarding guidelines and procedure for disposal of review cases and after obtaining confirmation/ verification from Pharmatrac.
- b. Ranitidine Syrup 75mg/5ml: In addition to the reply submitted above, NPPA representative further stated that the ceiling price of Ranitidine Syrup 75mg/5 ml was fixed based on data provided by AIOCD-AWACS / Pharmatrac for the month of August, 2015.

5. **Examination:**

NPPA has notified SO 1039(E), dated 1.4.2017 only for giving Annual Wholesale Price Index @ 1.97186% increase effective from 1.4.2017 to the scheduled formulations. (In supersession of this OM, NPPA issued another SO 2058(E), dt.30.6.2017 notifying revised ceiling prices by implementing GST w.e.f. 1.7.2017). The revision of ceiling prices are not against the review applications filed by the company.

Ranitidine Injection 25mg/ml:

The company had filed review petition under para 31 of DPCO, 2013 against SO 3431(E), dated 3.11.2016 vide which NPPA notified the ceiling price of the subject formulation. DoP has already issued Review Order on 4.5.2017 against the said review application and NPPA has also now implemented the Review Order, dt.4.5.2017 vide its SO 2401(E), dated 28th July, 2017. Therefore, the grievance of the company has already been settled. Moreover, SO 1039(E), dated 1.4.2017 has been notified by NPPA only to give WPI increase effective from 1.4.2017 to all the scheduled formulations.

Ranitidine Syrup 75mg/5ml:

The company had filed review petition under para 31 of DPCO, 2013 against SO 1561(E), dated 27.04.2016 vide which NPPA notified the ceiling price of the subject formulation. The review application was rejected by DoP being 'time barred' vide order No.31015/78/2016-PI.I., dated 19.9.2016. The request made by the company in its review application against SO 1039(E), dated 1.4.2017 cannot be considered as NPPA have notified the revision of the formulation under consideration only to give WPI increase effective from 1.4.2017 to all the scheduled formulations.

Review Orders against SO 3431(E), dated 3.11.2016 in respect of Ranitidine Injection 25mg/ml and against SO 1561(E), dated 27.4.2016 in respect of Ranitidine

Syrup 75mg/5ml, fixing the ceiling prices of the formulations have already been issued. SO 1039(E), dt.1.4.2017 is issued only to give WPI increase effective from 1.4.2017 to all the scheduled formulations and is not meant to fix the ceiling prices of the formulations, the grievances raised by the petitioner company have got no relevance.

6. **Government Decision:**

“Review Orders in respect of applications against earlier notifications fixing the ceiling prices of Ranitidine Injection 25mg/ml and Ranitidine Syrup 75mg/5ml have already been issued. SO 1039(E), dt.1.4.2017 is issued only to give WPI increase effective from 1.4.2017 to all the scheduled formulations and is not meant to fix the ceiling prices of the specific formulations. Therefore, the grievance raised by the petitioner company is dismissed.”

Issued on this date, the 30th day of October, 2017.

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

To

1. M/s. J.B. Chemicals & Pharmaceuticals Ltd.
“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