

No. 31015/33/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan,
New Delhi 110 001

ORDER BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO, 2013

Subject: The three review applications of M/s Fresenius Kabi India Private Ltd. dated 19.5.2016 under para 31 of DPCO against NPPA Notifications SO No.1560(E) dated 27.4.2016 and NPPA's working sheet related to price notified on 27.4.2016 for price fixation of "Paclitaxel injection, Carboplatin & Cisplatin".

Ref: 1) Review applications dated 19.5.2016
2) NPPA Notification under review S.O.No.1560(E) dated 27.4.2016 and NPPA's working sheets related to price notified on 27.4.2016
3) Record Note of Discussions of the personal hearing held on 5.7.2016

1. These are three petitions under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Fresenius Kabi India Private Ltd. (hereinafter called the petitioner) against notifications S.O.1560(E), dated 27/4/2016 and working sheets related to price notified on 27.4.2016, fixing the ceiling prices of "Paclitaxel injection, Carboplatin & Cisplatin" issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA).

2. The petitioner has contended for their each formulation as under:

For Paclitaxel Injection 30mg/5ml

- i. Under DPCO 2013, Paclitaxel Injection 30mg/5ml was notified as a scheduled products and its ceiling price was notified by S.O. 3338(E) dated 5th November, 2013.
- ii. The prices of the Captioned formulations were notified by NPPA from time to time are as follows:

Formulation	Dosage form	Strength	Unit	Ceiling Price (Rs)	Order No	Notification date
Paclitaxel Injection	Injection	30mg/5ml	Each pack	301.24	S.O. 3338(E)	05.11.2013
				320.28	S.O. 1156(E)	28.04.2014
				332.61	S.O. 619(E)	26.02.2015
				323.59	S.O. 644(E)	02.03.2016

			Per ml	207.08	S.O.1560(E)	27.04.2016
				207.08	Ceiling Price Computation	28.04.2016

For Carboplatin 10mg/1ml (150mg and 450mg)

- Under DPCO 2013, Carboplatin 10mg/1ml (150mg) was notified as a scheduled products and its ceiling price was notified by S.O. 1895(E) dated 28th June 2013.
- Under DPCO 2013, Carboplatin 10mg/1ml (450mg) was notified as a scheduled products and its ceiling price was notified by S.O. 1916(E) dated 28th June 2013.
- The prices of the Captioned formulations were notified by NPPA from time to time are as follows:

Formulation	Dosage form	Strength	Unit	Ceiling Price (Rs)	Order No	Notification date
Carboplatin	Injection	150mg vial	Each pack	789.01	S.O. 1895(E)	28.06.2013
				838.88	S.O. 1156(E)	28.04.2014
				871.17	S.O. 619(E)	26.02.2015
				847.56	S.O. 644(E)	02.03.2016
Carboplatin		10mg/1ml	Per ml	49.38	S.O.1560(E)	27.04.2016
				49.38	Ceiling Price Computation	28.04.2016
		450mg vial	Each pack	2424.93	S.O. 1916(E)	28.06.2013
				2578.19	S.O. 1156(E)	28.04.2014
				2677.42	S.O. 619(E)	26.02.2015
				2604.85	S.O. 644(E)	02.03.2016
		10mg/1ml	Per ml	49.38	S.O.1560(E)	27.04.2016
				49.38	Ceiling Price Computation	28.04.2016

For Cisplatin 1mg/1ml

- Under DPCO 2013, Cisplatin 1mg/1ml was notified as a scheduled products and its ceiling price was notified by S.O. 2241(E) dated 22nd July 2013.
- The prices of the Captioned formulations were notified by NPPA from time to time are as follows:

Formulation	Dosage form	Strength	Unit	Ceiling Price (Rs)	Order No	Notification date
Cisplatin	Injection	10mg/ vial	Each pack	84.84	S.O. 2241(E)	22.07.2013
				90.20	S.O. 1156(E)	28.04.2014

				93.67	S.O. 619(E)	26.02.2015
				91.13	S.O. 644(E)	02.03.2016
		1mg/1ml	Per ml	6.39	S.O.1560(E)	27.04.2016
				6.39	Ceiling Price Computation	28.04.2016

- iii. The price of the above mentioned formulation was notified by NPPA Price Notification Order No. 644(E) dated 2nd March, 2016 as per wholesale price index of -2.7105% and they have reduced the price of the said formulation accordingly to comply with the said price order (pursuant to per Para 16(4) of DPCO 2013).
- iv. Ceiling price notified vide above captioned order is not in accordance with the provisions of DPCO, 2013. Further reduction in price of the formulation by S.O. 1560(E) is erroneous and against the provisions of DPCO 2013 because for the said formulation the price notification as per Clause 16 (1) is already issued on 2nd March 2016.
- v. Further Paclitaxel Drug covered under sr. No. 36,37 and 38 of unique No. 8.1.29 of Ceiling price working sheet dated 28.04.2016 i.e. NANOXEL 30mg, NANOXEL 300mg and NANOXEL 100mg respectively are not conventional Paclitaxel Drug but Polymer Based Nano Particle Paclitaxel Drug. Hence they requested this Department to omit these formulations in calculating the ceiling prices of Paclitaxel.
- vi. As per para 11(3) of DPCO 2013 (notified by S.O. 1192(E) on 2nd April 2016 by NPPA) the Government may fix and notify separate ceiling price considering the type of packaging or pack size or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act 1940 (23 of 1940) and the rules made there under for the same formulation. However, while arriving at the ceiling prices of the formulations, the formulations with same strength / SKU are not considered.

In the light of the above and in the principle of natural justice, it is prayed that:

- (i) The notification no. S.O. 1560(E) dated 12th April 2016 w.r.t. Paclitaxel Injection 30mg/5ml, Carboplatin 10mg/1ml (150mg & 450mg), Cisplatin 1mg/1ml be withdrawn immediately and prices of aforesaid formulations be continue to be governed by the provisions of S.O. 644(E) dated 2nd March 2016.
- (ii) Fix the prices of formulations on the basis of pack size.

Comments of NPPA:

- (i) NPPA has fixed ceiling price for Carboplatin of Rs. 789.01 for 150mg per Vial (Per Pack) vide S.O. 1895(E) dated 28.6.2013. The same was revised to Rs. 838.88, Rs. 871.71 & Rs. 847.56 vide S.O. 1156(E) dated 28.4.2014, S.O. 619(E) dated 26.2.2015 & S.O. 644 (E) dated 2.3.2016 respectively under NLEM 2011. NPPA has also fixed the ceiling price of Rs. 2424.93 for

Carboplatin 450mg per Vial (Each pack) vide S.O. No. 1916 (E) dated 28.6.2013 the same was revised to Rs. 2578.19, 2677.42, & 2604.85 vide S.O. 1156 (E) dated 28.4.2014, 619 (E) dated 26.2.2015 & 644 (E) dated 2.3.2016 respectively under NLEM 2011, NPPA has also fixed the ceiling price of Rs. 49.38 /ml for Carboplatin 10mg/ml Vide S.O. 1560 (E) dated 27.4.2016 under NLEM 2015.

- (ii) Movement of ceiling price for Cisplatin Injection was as under:

Ceiling price of Rs.84.44 was fixed for Cisplatin Injection 10mg/vial (Per Pack) vide S.O. 2241(E) dated 22.7.2013. The same was revised to Rs. 90.20, Rs. 93.67 & Rs. 91.13 vide S.O. 1156(E) dated 28.4.2014, S.O. 619(E) dated 26.02.2015 & S.O. 644(E) dated 02.3.2016 respectively under NLEM 2011 and the same has been fixed to Rs. 6.39/ml for Cispatin 1mg/ml vide S.O. 1560(E) dated 27.4.2016 under NLEM 2015.

- (iii) On the same lines NPPA has fixed the ceiling price Rs. 301.24 for 30mg/5ml Paclitaxel Injection (Each Pack) and same was revised to Rs. 320.28, Rs.332.61 & Rs. 323.59 vide S.O. 1156 (E) dated 28.4.2014, 619 (E) dated 26.2.2015 & S.O. 644 (E) dated 2.3.2016 respectively under NLEM 2011 and the same has been again refixed as Rs. 207.08 for 30/ml vide S.O. 1560 (E) dated 27.4.2016 under NLEM 2015.
- (iv) Company's representation regarding ceiling price fixation for above said formulations under 11(3) of DPCO, 2013 is under examination.

6. In the personal hearing held on 5.7.2016, the petitioner furnished following submissions in respect of each of their product as under:–

CARBOPLATIN

1. Twice reduction of prices (for 150 mg – 55.61% **by S.O. 1895(E) dated 28.06.2013** & 13% **by 1560(E) dated 27.06.2013** and for 450mg- 32.16% **by S.O 1916(E) dated 28.06.2013** & 15% **by 1560(E) dated 27.06.2013**).
2. In working sheets different Packs are considered viz. **15 ML, 45ML & 60ML (though not qualified in calculation)** considered on equal footing for calculating simple average, which is not in accordance with DPCO 2013 para 4.
3. PTRs of 150 ml and 450 not matching with Form V of May 2015 and invoices.

CISPLATIN 10 mg

1. Twice reduction of prices (35.67% **by S.O. 2241(E) Dated 22.07.2013%** & 30% **by S.O. 1560(E) dated 27.04.2016**).

2. In working sheets different Packs are considered viz. **10 ml & 50 ml** considered on equal footing for calculating simple average, which is not in accordance with DPCO 2013 para 4.
3. PTRs of 10 ml in working sheet not matching with Form V and invoices.

PACLITAXEL INJECTION

1. Twice reduction of prices (50.06% by **S.O. 3338(E) dated 05.11.2013** & 36% by **S.O. 1560(E) dated 27.04.2016**).
2. ***Nanoxel is not conventional paclitaxel, and is a polymer based Nanoparticle paclitaxel and also it is not a scheduled drug, so Nanoxel should not be considered in the working sheet for ceiling price calculation of paclitaxel (unique no. 8.1.29).***
3. In working sheets different Packs are considered viz. **5ml, 50ml, 43.4ml, 16.7ml, 41.67, 17ml** considered on equal footing for calculating simple average, which is not in accordance with DPCO 2013 para 4.
4. PTRs of 17ml and 43.4 ml not matching with Form V and invoices.

The company representatives prayed that -

1. **SO No.1560(E), dated 27.4.2016 to be set aside and prices of the captioned formulations to be regulated by SO No.644(E), dated 2.3.2016.**
2. **All Packs of equal pack size and strength to considered for ceiling prices calculation and different price for different pack size as per para 11(3) of DPCO 2013 be granted.**
3. **Restrict the price revision to the new products added in NLEM and not further reduce the prices of products which are already in NLEM.**
4. **Nanoxel to be excluded from working sheet as it is not a scheduled product.**

NPPA representative submitted that:

1. The earlier notifications were based on NLEM 2011 and the change in ceiling price due to recent notifications are based on NLEM 2015 in respect of all the concerned formulations. Hence, it is as per the provisions of DPCO 2013.
2. NLEM 2011 in respect of the concerned formulations is based on per pack and NLEM 2015 is based on strength of the formulation per unit. Accordingly, the ceiling price fixation under NLEM 2015 is based on the strength of formulation per unit and hence the consideration of different pack sizes is irrelevant in the calculation of ceiling price.

3. As per para 18 of DPCO 2013, revision of ceiling price is carried out as and when the NLEM is revised by the Ministry. Accordingly, the ceiling price has been fixed as per NLEM 2015.
4. In DPCO 2013, there is no provision for separate consideration of Nanoxel and hence has been included in the working sheet.

5. **Examination:**

The said review petitions were filed against S.O. No.1560(E) dated 27.4.2016 for fixation of the ceiling prices under DPCO, 2013, due to amendment in Schedule-I of DPCO, 2013 on 10th March, 2016 using Para 17 & 18 of DPCO, 2013. In this regard, it is observed that the ceiling prices of all the three products were fixed on 5.11.2013, 28.6.2013 & 22.7.2013 after announcement of the DPCO, 2013. After that the ceiling price revised upward two times on 28.4.2014 & 26.2.2015 due to change of WPI as Para 16 of DPCO, 2013 and ceiling price revised downward one time on 2.3.2016 due to reduction in WPI. Hence, the issue raised by the petitioner company has no merit.

The base PTR price for all the three cases for all Division prices is old one, i.e. of May, 2012 and the ceiling price revised per pack and not per ML, but due to amendment in Schedule-I, the revision in the ceiling price is based on per ML basis and by considering the new PTR of all products (Aug, 2015), combined with all different pack sizes such as 5ml, 30ml, 50ml & 100ml etc., which is not correct. Company in its representations stated that the ceiling price for all the products should be fixed per ml for each pack size as per Para 11(3) of DPCO, 2013.

As regards company's request for separate ceiling price for the formulations as per para 11(3) of DPCO, 2013, notified by SO 1152(E), dated 2.4.2016, the company representatives prayed that all packs of equal pack size and strength to be considered for ceiling price calculation and different price for different pack size as per para 11(3) of DPCO 2013 be granted. In this connection, para 11(3) of DPCO, 2013 may kindly be read as under:-

“(3) Notwithstanding anything contained in sub-paragraph (1) and (2), the case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I of the Drugs (Prices Control) Order, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specific therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specified in

the Drugs and Cosmetic Act, 1940 (23 of 1940) and the rules made thereunder for the same formulation.”

The NPPA representative, during the hearing, stated that company's representation regarding ceiling price fixation for above said formulations under para 11(3) of DPCO, 2013 is under examination.

After hearing the company as well as NPPA, hearing authority is of the opinion that NPPA may be directed to re-examine all the three cases and re-fix/revise the ceiling price under para 11(3) of DPCO, 2013, if considered necessary.

6. Government decision:

NPPA is directed to revise the prices within one month of this order of all the three cases of the petitioner company in the light of para 11(3) of DPCO, 2013 and strictly in accordance with para 4 of DPCO 2013.

The present review petition stands disposed off.

Issued on this, the 19th day of September, 2016.

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

To

1. M/s. Fresenius Kabi India Private Ltd.,
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2. The Member Secretary,
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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