

No. 31015/12/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan,
New Delhi 110 001

ORDER BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO, 2013

Subject: The review applications of M/s Fresenius Kabi India Private Ltd. dated 25.4.2016 under para 31 of DPCO against NPPA Notifications SO No.1404(E) and SO No.1405(E) dated 12.4.2016 for price fixation of “Gemcitabine Hydrochloride Injection (1 ml)” and “Filgrastim Injection (1 ml)”.

Ref:

- 1) Review applications dated 25.4.2016
- 2) NPPA Notifications under review S.O.No.1404(E) & 1405(E), dated 12.4.2016
- 3) Record Note of Discussions of the personal hearing held on 26.5.2016

1. These are two 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.1404(E), dated 12/4/2016 fixing the ceiling prices of “Gemcitabine Hydrochloride Injection (1 ml)” and S.O.1405(E) dated 12/04/2016 fixing ceiling prices of “Filgrastim Injection (1 ml)”, issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA).

2. The petitioner has contended for their formulation Gemcitabine Hydrochloride Injection (1mg):

- (i) Their formulation Gemcitabine Hydrochloride Injection (1mg) was notified as a scheduled products and its ceiling price was notified by S.O 1611(E) dated 14/06/2013. The prices of the Captioned formulations were notified by NPPA from time to time are as follows:

Formulation	Dosage form	Strength	Unit	Ceiling Price	Order No	Notification date
Gemcitabine Hydrochloride	Injection	1 gm	Each Pack	5969.16	1611(E)	14/06/2013
				6346.41	1156(E)	28/04/2014
				6590.68	619(E)	26/02/2015
				6412.04	644(E)	02/03/2016
				4922.43	1404(E)	12/04/2016

- (ii) As per Clause 16 (1) of DPCO 2013, The Government shall revise the ceiling prices of scheduled Formulations as per the Annual Wholesale Price Index (WPI), every year before 1st April.
- (iii) As per Para 13 (3) of the DPCO 2013, if the price of any product has been fixed and notified, the existing manufacturer is allowed to increase the price based on Wholesale Price Index (WPI) as per the provisions of Para 16 (2) & (3) or need to decrease the price based on Wholesale Price Index (WPI) as per Para 16 (4) of DPCO 2013.
- (iv) On 10/03/2016 Government (DOP) has amended Schedule- 1 of DPCO, 2013 vide S.O. 701 (E) by incorporating formulations under NLEM, 2015. Therefore, NPPA is mandated to revise the ceiling price of the Scheduled formulations under para 17 of DPCO, 2013. Accordingly, NPPA has revised the ceiling price Rs. 6412.04 (fixed vide SO No.644(E), dt.2.3.2016) to Rs. 4922.43 vide S.O. 1404(E) dated 12.4.2016 under para 4, 10, 11, 14, 16, 17 and 18 of DPCO, 2013.

The petitioner requested this Department that the ceiling price of the abovesaid formulation should not be governed under price notification SO 1404(E) and requested to continue the ceiling price to be governed by the provisions of SO 644(E) dated 2.3.2016.

3. A copy of the review petition was sent to the NPPA vide its letter dated 9th May, 2016, which submitted its comments vide its letter dated 25.5.2016, as under :-

- (i) Gemcitabine Hydrochloride Powder for Injection (1gm) is included under section 8.2.14.1 of NLEM 2011 and 8.1.21.2 of NLEM 2015 under DPCO, 2013. NPPA is mandated to fix the ceiling price of Scheduled formulations under NLEM & NLEM 2015. Accordingly, NPPA fixed the ceiling price for this formulation vide S.O. 1611(E) dated 14.6.2013, S.O. 1156(E) dated 28.4.2014, S.O. 619(E) dated 26.02.2015, S.O. 644(E) dated 02.3.2016 & S.O. 1404(E) dated 12.4.2016.
- (ii) DPCO, 2013 has been issued under section 3 of Essential Commodities Act, 1995 NPPA is mandated to fix the reasonable, fair and affordable prices to the consumers as per the provisions of DPCO, 2013 therefore the request of the company to withdraw S.O. 1404(E) dated 12.04.2016 cannot be considered by this office.

4. In another petition, the petitioner contended for their formulation Filgrastim Injection (1 ml) as under:

- (i) Their formulation Filgrastim Injection 1ml was notified as a scheduled products and its ceiling price was notified by S.O 1897(E) dated 28/06/2013.
- (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	Order No	Notification date
Filgrastim	Injection	1 ml vial	1 ml	2142.79	1897(E)	28.06.2013
				2278.21	1156(E)	28.04.2014
				2365.90	619(E)	26.02.2015
				2301.00	644(E)	02.03.2016
	300 mcg	Each pack	1273.00	1405(E)	12/04/2016	

- (iii) As per Clause 16 (1) of DPCO 2013, The Government shall revise the ceiling prices of scheduled Formulations as per the Annual Wholesale Price Index (WPI), every year before 1st April.
- (iv) As per Para 13 (3) of the DPCO 2013, if the price of any product has been fixed and notified, the existing manufacturer is allowed to increase the price based on Wholesale Price Index (WPI) as per the provisions of Para 16 (2) & (3) or need to decrease the price based on Wholesale Price Index (WPI) as per Para 16 (4) of DPCO 2013.
- (v) Vide S.O. 701(E) dated 10.3.2016, (DoP) has amended Schedule-I of DPCO, 2013 by incorporating formulations under NLEM 2015. Filgrastim Injection 1ml containing 300mcg was reclassified and added as Filgrastim Injection 300mcg in NLEM 2015. Therefore, NPPA is mandated to revise the ceiling price of the Scheduled formulations under para 17 of DPCO, 2013. Accordingly, NPPA has revised the ceiling price Rs. 2301.00 (fixed vide SO No.644(E) dt.2.3.2016) to Rs. 1273.00 vide S.O. 1405(E) dated 12.4.2016 under para 4, 10, 11, 14, 16, 17 and 18 of DPCO, 2013.

The Petitioner requested this Department that the ceiling price of the abovesaid formulation should not be governed under price notification SO 1405(E) and requested to continue the ceiling price to be governed by the provisions of SO 644(E) dated 2.3.2016.

5. A copy of the review petition was sent to the NPPA, vide its letter dated 10th May, 2016, which submitted its comments vide its letter dated 25.5.2016, as under :-

- (i) Filgrastim Injection 1ml is included under section 8.3.6.1 of NLEM 2011 and 8.4.5.1 of NLEM 2015 under DPCO, 2013. NPPA is mandated

to fix the ceiling price of Scheduled formulations under NLEM 2011 & 2015. Accordingly, NPPA fixed the ceiling price RS. 1273.00 for Filgrastim Injection 300mcg vide S.O. 1405(E) dated 12.04.2016.

- (ii) DPCO, 2013 has been issued under section 3 of Essential Commodities Act, 1995 NPPA is mandated to fix the reasonable, fair and affordable prices to the consumers as per the provisions of DPCO, 2013, therefore, the request of the company to withdraw S.O. 1405(E) dated 12.04.2016, cannot be considered by this office.

6. In the personal hearing held on 26.5.2016, the petitioner stated that para 18(1) has been interpreted in a literal manner without considering the implications for all the stakeholders. They submitted that it would not be logical to re-fix the ceiling prices of Existing Scheduled Formulations merely because new drugs have been added to Schedule I, as the new drugs are independent of the Existing Scheduled Formulations. They also submitted that repeated and persistent reduction of ceiling prices would reduce the ceiling prices to the lowest possible number very soon for all manufacturers. Accordingly, small manufacturers who do not incur R&D Expenditure and who operate at minimum acceptable level of quality and offer products at cheaper price would only survive and major players who incur all these expenditure will leave / exit the market. The petitioner also submitted that as per para 4 of DPCO 2013, the calculation of ceiling price of scheduled formulation, while calculating the Simple Average price to retailer companies having 1% or more of total market share, are to be considered . They have submitted two working sheets showing that in working sheet for ceiling price notification dated 12.4.2016, unique NO.8.4.5 for Filgrastim, in case of Emcure which has 2 products EGRAST & MGRAST with different market share i.e. 0.50% and 4.90% there NPPA has combined both strengths and taken the market share as 5.40% and qualified both products for calculation. However, in case of Gemcitabine, the same case exist with Sun Pharma and is not considered where Sun Pharma has 2 products with XTROZ & GEMTAZ with market share of 0.71% and 8.92% respectively but NPPA has not applied similar calculation process. The company requested to apply the same method in Gemcitabine Hydrochloride Injection as that of Filgrastim Injection and include Sun Pharma in calculation.

7. The NPPA representative stated that the matter may be considered by the concerned authority in case it is within the purview of provisions of DPCO 2013 and is as per existing guidelines of the Authority.

8. In the personal hearing, the petitioner also raised the point that in case of Filgrastim, they saw that both pre-filled syringe and injection is taken in same calculation sheet, having different therapeutic use.

9. The NPPA representative stated that the petitioner company may approach NPPA specifying the therapeutic advantages of pre-filled syringes versus vial. Thereafter, the matter may be referred to Expert Committee in NPPA to examine in line of amended para 11(3) of DPCO, 2013, subject to the concurrence of the Authority. The company representatives consented to submit their representation to NPPA soon.

10. **Government decision:**

NPPA was directed to examine the additional submissions to be provided by the Company on merit and take appropriate decision in the matter.

In view of the above, the present review petition stands disposed off.

Issued on this 4th day of August, 2016.

(M.K. Bhardwaj)

Deputy Secretary

For and on behalf of the President of India

To

1. M/s. Fresenius Kabi India Private Ltd.,
5th Floor, A wing, Ashoka Plaza, Pune Nagar Road,
Survey No.32/2, Vadgaon Sheri,
Viman Nagar, Pune-411014.
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