

No. 31015/82/2017-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 Fresenius Kabi India Private Limited against price fixation of “Ringer Lactate Injection” vide NPPA order No. S.O. 2401(E), dated 28.07.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 17.08.2017
2) NPPA notification under review S.O. 2401(E), dated 28.07.2017
3) Record Note of discussions held in the personal hearing held in the matter on 12.12.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Fresenius Kabi India Private Limited (hereinafter called the petitioner) against notification S.O. No.2401(E), dated 28.07.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Ringer Lactate Injection.

2. The petitioner has contended as under:-

I. Under DPCO 2013, the formulations, **IV Fluid viz. Ringer Lactate**, notified as a scheduled products and its ceiling price was notified by S.O. 2863(E) dated 20.09.2013. The prices of the Captioned formulation was notified by NPPA subsequently by price notification viz. S.O. 1156(E) dated 28.04.2014, SO. 619(E) dated 26.02.2015 and S.O. 2060(E) dated 30.06.2017.

II. In the working sheet issued by NPPA regarding the price notification S.O. 2401(E) dated July 28, 2017 has not calculated the ceiling price of captioned IV Fluids viz. **Ringer Lactate** according to Paragraph 4 of DPCO. The reasons for the same are as follows:

A. In Case of Ceiling price calculation of 500 ml:

NPPA while fixing the ceiling price of 500 ml pack has considered the ceiling price of Rs. 46.20 as per notification No. S.O. 1291(E) dated 4th June, 2008 wherein the ceiling price of the Ringer Lactate 500 ml was fixed due to violation of provisions of DPCO 1995 by Nirma Limited. The provision in DPCO 2013 requires NPPA to fix the ceiling price based on the simple average price mechanism.

Further applying the PTR derived from SO. 1291(E) dated 4th June, 2008 has considerably reduced the PTR in many cases such as Claris Life Sciences, Amanta Healthcare, Pantagon Labs Ltd. thereby reducing the average PTR.

B. In case of Ceiling price calculation of 1000 ml and 250 ml:-

(i) NPPA has restricted the ceiling price using the formula as recommended by Pronab Sen Committee Report. There is no provision in DPCO 2013 regarding using such formula and using this type of method is completely against the provisions of DPCO 2013 as Pronab Sen Committee report is only recommendatory and is not a law in itself.

(ii) Further Pronab Sen Committee report was issued on September 20, 2005 i.e. 8 years before DPCO 2013.

(iii) NPPA has not followed the method prescribed under DPCO 2013 to arrive at the ceiling price based on simple average market price.

III. Further as per Para 11(3) the Government may fix separate ceiling price or retail price of the formulations considering the type of packaging or pack size etc. However NPPA has categorized the said formulation under the single type and fixed the uniform price for all types of packs unlike the other IV fluids i.e. Normal Saline, Glucose Injection 5% and Glucose Injection 5% + Normal Saline wherein the separate ceiling price is fixed in to 3 categories Glass, Non Glass and Non Glass with Special Features.

IV. In connection with the above, company submitted the following facts:

Position under DPCO 1995:

(i) DPCO 1995 and NPPA vide S.O. 2710(E) dated 28.11.2011 and S.O. 2151(E) dated 20th September 2011, had categorized the pack of the IV Fluids into

- a. Glass Bottle Packaging
- b. FFS/ BFS/Plastic/ PVC Bottles
- c. FFS/ BFS/Plastic/ PVC Bottles with **Eurohead**
- d. Non PVC bags

(ii) Under DPCO 1995, the ceiling price of EUROHEAD packs was fixed in reference to price of Plastic bottles. S.O. 2710(E) dated 28.11.2011 provided for an additional amount (above normal plastic bottle pack) of Rs.1.33 for pack upto 100ml and Rs.2.96 for pack above 100ml for EUROHEAD packs.

(iii) Under DPCO 1995 the ceiling price of Non PVC Bags was fixed independent of the price of Plastic bottles or Plastic bottles with Eurohead.

Position under DPCO 2013:

(a) The NPPA by its notification dated 24th June, 2016 notified the separate pricing for the I.V. Fluids by classifying them into glass, non-glass and non- glass with special feature.

(b) However the same method is not followed in case of captioned formulation.

V. Company further submitted that **para 18** of DPCO 2013 *NPPA can revise ceiling price only after 5 years or after revision of NLEM List by Ministry of Health and Family Welfare whichever is earlier.*

VI. Company also referred to the **Office memorandum dt. 20/04/2017 with reference F. NO.: 31026/31/2016-PI.I (Pt. IV)**, issued by Department Of Pharmaceuticals, directing NPPA not to review ceiling price before 5 years. Constant uncertainty and revision of prices would make the business unviable and erode the confidence of industry to make investments in improving the products for the benefit of patient.

VII. In view of the above, company prayed as under:-

(i) **Re-calculate the Ceiling prices for Ringer Lactate in Non - Glass pack with Special Features** as done in case of other fluids so as to make it financially viable for the manufacturers to manufacture the said formulation. Company also requested to have a separate category for Ringer Lactate in Non PVC bags and not combine our Freeflex bag (Non PVC bags) in same category as non-glass bottle packs with special features.

(ii) Re-calculate the Ceiling prices for Ringer Lactate using **simple average method** provided in paragraph 4 of DPCO 2013.

3. Comments of NPPA:

I. Ceiling price of **Ringer Lactate Injection** was notified as Rs. 41.17/500ml pack, Rs. 72.38/1000ml pack, Rs.18.95/100 ml and Rs. 32.31/250 ml vide S.O. 2401(E) dated 28.07.2017 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 **Ringer Lactate 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 that NPPA notified ceiling price for Ringer Lactate Injection vide S.O. 2863(E) dated 20.09.2013 and the same was revised by NPPA vide S.O. 1156 (E) dated 28.04.2014, S.O. 619 (E) dated 26.02.2015 and S.O. 2060 (E) dated 30.06.2017. Company also reiterated that NPPA has not calculated the ceiling price of Ringer Lactate Injection according to para 4 of DPCO, 2013. Following points were submitted by company in support of their claim.	NPPA fixed ceiling price of Ringer Lactate Injection as Rs. 41.17/500ml pack and Rs. 72.38/1000ml, Rs.18.95/100ml and Rs.32.31/250 ml pack vide S.O. 2401(E) dated 28.07.2017 as per the directions given by DOP vide review order no. 31015/9/2015-PI.I dated 05.05.2016 against the review filed by M/s. Fresenius Kabi India Pvt. Ltd. DOP vide review order no. 31015/9/2015-PI.I dated 05.05.2016 passed an order along with other 8 representations to examine the case in light of S.O.

<p><u>A). In case of ceiling price calculation of 500 ml:</u></p> <p>NPPA while fixing the ceiling price of 500 ml pack has considered the ceiling price of Rs. 46.20 as per notification number 1291 (E) dated 04th June, 2008 wherein, the ceiling price of Ringer Lactate 500 ml was fixed due to violation of provisions of DPCO, 1995 by M/s. Nirma Ltd. While provisions in DPCO, 2013 requires NPPA to fix the ceiling price based on the simple average price mechanism. Further, applying the PTR derived from 1291 (E) dated 04th June, 2008 has considerably reduced the PTR in many cases such as Claris Life sciences, Amanta Healthcare and Pentagon Labs Ltd.</p> <p><u>B). In case of ceiling price calculation of 1000 ml and 250ml:</u></p> <p>NPPA has restricted the ceiling price using the formula as recommended by Pronab Sen committee report. There is no provision in DPCO, 2013 regarding using such formula and using this type of method is completely against the provision of DPCO, 2013 as Pronab Sen committee report is only recommendatory and is not a law in itself. Pronab Sen committee report was issued on 20th Sep, 2005 i.e., 8 years before DPCO, 2013. NPPA has not followed the simple average market price as mentioned in DPCO, 2013 to arrive at the ceiling price. Further, NPPA has not followed the practice to fix the separate ceiling price or retail price of the formulations considering 3 categories viz. Glass, Non-Glass and Non-Glass with special feature as was followed in fixing the ceiling price for other IV fluids i.e. Normal Saline, Glucose Injection 5% and Glucose Injection 5%+ Normal</p>	<p>1192(E) dated 22.03.2015 under para 11(3) of DPCO 2013.</p> <p>NPPA uploaded draft-working sheet of proposed ceiling price of this formulation on its website. The draft-working sheet placed on the website of NPPA on 16.06.2017 i.e. 40 days before price notification. M/s. Fresenius Kabi India Pvt. Ltd. did not make any representation/request against the proposed retail price uploaded on NPPA website considering special feature pack for subject formulation.</p> <p>Reference is invited to review order no. 31015/74/2012-PI.I and 31015/75/2012-PI.I dated 17.02.2014 wherein DOP rejected the review application of M/s B. Braun Medical India Pvt. Ltd. and M/s. Baxter (India) Pvt. Ltd. against S.O. 2863(E) dated 20.09.2013 requesting for a separate pricing for separate packaging material in respect of the price fixation of Ringer Lactate Injection. Similarly, DOP vide review order no. 31015/40/2014-PI.I dated 05.08.2014 rejected the review application of M/s. Fresenius Kabi India Pvt. Ltd. against S.O. no. 1156(E) dated 28.04.2014 requesting for separate pricing for separate packaging material in respect of the price fixation of Ringer Lactate Injection. On the issue whether the variants available in the market have different therapeutic efficacy, the case pertaining to M/s Baxter and M/s. B. Braun have already been referred to Standing Technical Committee. Ringer Lactate is appearing in DPCO, 1995 as well as under DPCO, 2013 (NLEM 2011 and 2015) which is a common drug. NPPA fixed the ceiling price for subject formulation in order to implement the Review order no. 31015/9/2015-PI.I dated 05.05.2016. Therefore, issues raised by company have no merit.</p> <p>NPPA has implemented the Review order no. 31015/9/2015-PI.I dated</p>
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	<p>Saline.</p> <p>Company also submitted the salient features considered by NPPA while fixing the ceiling price of IV fluids under DPCO, 1995.</p> <p>Company also stated that NPPA should not revise the ceiling price of this formulation after 5 years as per para 18 of DPCO, 2013.</p>	05.05.2016.
		The products are not appearing in the Pharmatrac.

III. Company has not challenged S.O. No. 2401(E) dated 28.07.2017 in any Court.

5. **Examination:**

The company has stated that NPPA by its notification dated 24th June, 2016 notified the separate pricing for the IV fluids by classifying them into glass, non-glass and non-glass with special features. However, the same method was not followed in case of captioned formulation. Company requested to have a separate category for Ringer Lactate in Non PVC bags and not combine their Freeflex bag (Non PVC bag) in same category as non-glass bottle packs with special features.

5.2 It is observed that NPPA has fixed the ceiling price of subject formulation based on pack sizes, i.e. 100ml, 250ml, 500ml and 1000ml. However, type of packaging was not taken into account by NPPA while fixing the ceiling prices on the ground that there is no provision in DPCO to consider separate pricing on the basis of cost of packaging. NPPA invited the reference of Review Orders No.31015/74/2012-PI.I and 31015/75/2012-PI.I, dated 17.2.2014, in respect of M/s B.Braun Medical India Pvt. Ltd. and M/s Baxter (India) Pvt. Ltd. against SO 2863(E), dated 20.09.2013 and Review Order No.31015/40/2014-PI.I, dated 05.08.2014 in respect of M/s Fresenius Kabi India Pvt. Ltd. against SO No.1156(E), dated 28.4.2014 wherein DoP rejected the review applications of companies requesting separate pricing for separate packaging material in respect of price fixation of Ringer Lactate Injection.

5.3 It may be mentioned here that in DPCO, 2013, there was no provision of examination by Committee of Experts in the year 2014 when the review orders, referred to above by NPPA, were issued by DoP. However, vide SO 1192(E), dated 22.03.2016, para 11(3&4) were inserted in DPCO, 2013, wherein **a provision was made to form a Committee of Experts**, which reads as under:-

“11(3) Notwithstanding anything contained in sub-paragraph (1) and (2), in 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 specified 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 Pharmacopoeia

or other standards as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder for the same formulation.

11(4) *The Government shall form a Committee of Experts, as it may deem fit, within a period of fifteen days from the date of issue of this order, to recommend fixing of separate ceiling price of scheduled formulations or retail price of a new drug as per the above parameters.”*

5.4 It would be seen therefrom that the Committee of Experts is formed to consider and give its recommendation on **notifying separate ceiling price or retail price** for such formulations with specified 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. In the instant case, **before fixing the ceiling price of Ringer Lactate Injection, NPPA has not taken the opinion of Committee of Experts.**

5.5 It is worth mentioning here that earlier various companies filed review applications in 2013, 2014 and 2015 for fixation of ceiling price of IV fluids based on type of packaging against NPPA's notifications fixing ceiling price of IV fluids [Glucose 5%, Normal Saline Injection (Sodium Chloride 0.9%) and Ringer Lactate Injection] vide SOs No.2863(E), dated 20.9.2013; 3127(E), dated 10.12.2014 and 3131(E), dated 10.12.2014. The list of such companies is as under:-

- i) M/s Fresenius Kabi India Pvt. Ltd. – petition dt.7.1.2015 against SO 3127(E), dt.10.12.2014 fixing ceiling price of Glucose and Sodium Chloride.
- ii) M/s Amanta Healthcare Pvt. Limited – petition, dt.29.12.2014 against SO 3127(E), dt.10.12.2014 fixing ceiling price of Glucose and Sodium Chloride.
- iii) M/s B.Braun Medical (India) Limited – petition, dt.18.10.2013 against SO 2863(E), dt.20.9.2013 fixing ceiling price of Ringer Lactate Injection.
- iv) M/s Claris Otsuka Pvt. Limited – petition, dt.8.1.2015 against SO 3127(E), dt.10.12.2014 fixing ceiling price of Glucose and Sodium Chloride.
- v) M/s B.Braun Medical (India) Limited – petition, dt.7.1.2015 against SO 3127(E), dt.10.12.2014 fixing ceiling price of Glucose and Sodium Chloride.
- vi) M/s KrishnaKeshav Laboratories Limited – petition, dt.29.12.2014 against SO 3127(E), dt.10.12.2014 fixing ceiling price of Glucose and Sodium Chloride.
- vii) M/s Nirma Limited (Healthcare Division) – petition, dt.5.1.2015 against SO 3127(E), dt.10.12.2014 fixing ceiling price of Glucose and Sodium Chloride.
- viii) M/s Ahlcon Parenterals Limited – petition, dt.7.1.2015 against SO 3127(E), dt.10.12.2014 fixing ceiling price of Glucose and Sodium Chloride.
- ix) M/s AXA Parenterals Ltd. – petition, dt.7.1.2015 against SO 3127(E), dt.10.12.2014 fixing ceiling price of Glucose and Sodium Chloride.

5.6 Keeping in view the similar nature of grievance of above pharma companies for fixation of separate ceiling price of IV fluids based on types of packaging, DoP, vide its Order No.31015/9/2015-PI.I, dated 5th May, 2016, directed NPPA to examine the review applications of above pharma companies under para 11(3&4) of DPCO, 2013.

5.7 On the direction of DoP, NPPA referred the matter to Committee of Experts, and based on the recommendation of the Committee, separate ceiling prices of two types of

IV fluids, i.e Glucose and Sodium Chloride for Glass, PVC and Non-PVC packaging were fixed vide SO No.1993(E), dated 3.6.2016.

5.8 Later on, the following IV fluid manufacturing companies represented for fixation of separate ceiling prices based on different types of packaging as glass, non-glass and non-glass with special features:-

- i) M/s B.Braun Medical(I)Pvt. Ltd. manufacturing Ecoflac Plus bottle with Eurohead;
- ii) M/s Amanta Healthcare Ltd. manufacturing Steriport bottle;
- iii) M/s Aculife Healthcare Pvt. Ltd. manufacturing Aculife bottle with Eurohead;
- iv) M/s Albert David Limited manufacturing Albert David bottle with Eurohead;
- v) M/s Denis Chem Limited manufacturing Aquapulse with Eurohead;
- vi) M/s Claris Life Sciences Limited manufacturing Claris bottle with Eurohead;
- vii) M/s Fresenius Kabi India Pvt. Limited manufacturing Freeflex bags; and
- viii) M/s Claris Otsuka Private Limited manufacturing Unibag.

5.9 Based on the representations from above company and feedback from various glass and non-glass manufacturers and on its own examination, NPPA modified the previous categorization of different types of packaging as glass, non-glass and non-glass with special features. Accordingly, NPPA re-fixed the ceiling price of aforesaid formulation for category of glass and non-glass vide SO 2209(E), dated 24.6.2016 and for non-glass with special features vide SO 2210(E), dated 24.6.2016. The above categorization based on types of packaging covered only Glucose and Sodium Chloride, but did not contain 'Ringer Lactate Injection', which is also in the category of IV Fluid.

5.10 Glucose, Sodium Chloride and Ringer Lactate are the various types of IV fluids having similarity in nature. NPPA has fixed the separate ceiling prices of only two types of IV fluids, i.e. Glucose and Sodium Chloride, based on different type of packagings. However, in the case of Ringer Lactate, only type of fluid is changing and not the containers. Different methodology cannot be followed with the similar nature of IV fluids.

5.11 In view of the above, as was done in the case of other IV Fluids, NPPA may be directed to refer the matter to Committee of Experts for fixation of separate ceiling prices of Ringer Lactate Injections considering type of packaging, as per provision in para 11(3&4) of DPCO, 2013. On the basis of recommendations of the Expert Committee, separate prices may be fixed for subject formulation.

6. **Government Decision:**

“NPPA is hereby directed to refer the matter to Committee of Experts for examination of the claim of fixation of separate ceiling prices of Ringer Lactate Injections considering the types of packagings, as per para 11(3&4) of DPCO, 2013, after giving an opportunity to the petitioners to represent their case before the Committee of Experts. On the basis of recommendations of the Committee of Experts, appropriate decision may be taken on pricing of the subject formulation within a month by the NPPA.”

Issued on this date, the 21st day of March, 2018.

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

To

1. M/s Fresenius Kabi India Private Limited,
Fifth Floor, A Wing, Ashoka Plaza,
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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