

**No. 31015/84/2017-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 B.Braun Medical (India) Pvt. 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 25.08.2017  
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 31.10.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s B.Braun Medical (India) Pvt. 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. Ceiling price of ringer Lactate Injection I.P. was fixed vide S.O. No. 2863(E) dated 20/09/2013 at Rs. 0.10 per ml. As per S.O. the price first time fixed for any pack- either Glass or Poly (LDPE).

II. NPPA revised Ceiling price of Ringer Lactate Injection I.P. vide S.O. No. 1156(E) dt. 28/04/2014 @ Rs. 0.11 per ml. This price was also for any pack-Glass or Non Glass.

III. As per S.O. 1192(E) dt.22/03/2016 NPPA amended para11 by inserting 2 sub paras. As per sub para 11(3) of the DPCO 2013, NPPA has been authorized to fix separate ceiling price in respect of various variants, of which one is 'type of Packaging'.

IV. After amendment supra, NPPA fixed few meetings and few manufacturers demonstrated packs of different forms of different Glass & Non Glass with special features.

V. NPPA fixed higher ceiling price for PVC & Non PVC under para 11(3) of DPCO 2013 as per S.O.1993(E) dt. 03/06/2016 and Glass & Non Glass with special features' as per S.O. 2210(E) dt. 24/06/2016 - for 8 products and for 8 manufacturers. The said S.O. also did not contain product 'Ringer Lactate injection I.P.'

VI. As per S.O. 2209(E) dt.24/06/2016, NPPA fixed ceiling price of 'Glass' & 'non-Glass with special features'. Incidentally, this S.O. also do not cover product 'Ringer Lactate Injection I.P.'

VII. Review Order 31015/9/2015-PI.I dt. 05/05/2016 was having one review application dt. 18/10/2013 filed against S.O. 2863(E) dt. 20/09/2013. The said review application was disposed off with a direction to examine in the light of S.O. 1192(E) dt. 22/03/2016. Thus NPPA was expected to review ceiling price under para 11(3) of DPCO 2013, to fix separate ceiling price for 'special packaging' but not for packaging for which ceiling price was fixed. NPPA did not do so, while revising ceiling price under S.O.—dt. 28/07/2017. Thus portion of S.O. is liable to be withdrawn.

VIII. As per SO 1993 (E) dt 03.06.2016, NPPA notified prices of various IV fluids based on packaging, various packaging & special features mentioned in the Note 'E' of the said notification.

IX. NPPA issued fresh notification, SO 2210(E) dt 24.06.2016, refixing the prices of various IV fluids including Ecoflac plus self collapsible closed system infusion containers. The said notification was set aside by your office vide order dt 19.09.2016 after we had filed a review application dt 13.07.2016.

X. S.O. dt. 28/07/2017 has only 4 packs of Ringer Lactate Injection I.P.—100ml/250ml/500ml/1000ml. All these packs were covered under one S.O. as well earlier. There is no mention of '**Type of Packaging**' in the S.O. dt. 28/07/2017. Had NPPA fixed ceiling prices for Glass/Non-PVC/ non-glass special features, company could have understood that NPPA had considered '**type of packaging**' and fixed ceiling price in compliance of Review Order no. 31015/9/2015-PI.I. dt. 05/05/2016. But there appears unilateral revision in ceiling price in the guise of para 11(3) of DPCO 2013, which otherwise not available under para 16 of the DPCO 2013. Thus portion of S.O. is liable to be withdrawn.

XI. As per NPPA's O.M. No. 8(34)/2016/DP/NPPA/Div.II dated 16.06.2017, draft working were notified, with intention to revise ceiling price of Ringer Lactate. On perusal of working it has been noticed that NPPA has considered price under DPCO 1995. When ceiling price had been notified under DPCO 2013, vide S.O. 2863(E) dt. 20/09/2013, there is no logic to either compare ceiling price under DPCO 1995 or consider ceiling price of 2011.

XII. In June 2017 more so, in view of direction as per Office memorandum of DOP, **GOI dt. 20/04/2017** under file reference 31026/31/2016-PI.I (pt.iv) which reads — "**we directs NPPA not to review ceiling price before 5 years**". The intention to review ceiling price is contrary to directions of DOP, GOI as well as para 16 of the DPCO 2013. Thus portion of S.O. is liable to be withdrawn.

XIII. As per para 16 of the DPCO 2013, NPPA can revise Ceiling price after 5 years from date of S.O. no. 2863(E) {dt. 20/09/2013} but not before 20/09/2018. Accordingly, company find that NPPA has exercised powers not vested under DPCO 2013 para 16 But arbitrarily revised price on 28/07/2017, for all packs, contrary to DPCO 2013. Thus, portion of S.O. is liable to be withdrawn.

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

Sr.no.15, 16, 17 & 18 of the S.O. 2401 (E) dt. 28<sup>th</sup> July 2017, be withdrawn immediately.

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	<p>Company has stated that NPPA first time fixed ceiling price Rs. 0.10/ml for <b>Ringer Lactate Injection</b> vide S.O. 2863(E) dated 20.09.2013 for any pack – either glass or poly (LDPE) and the same was revised to 0.11/ml vide S.O. 1156(E) dated 28.04.2014 for any pack – either glass or poly (LDPE).</p> <p>As per S.O. 1192(E) dated 22.03.2016, NPPA amended para 11 by inserting to sub-paras. As per para 11(3) of DPCO, 2013, NPPA has been authorized to fix separate ceiling price in respect of various variants of which one is type of packaging.</p> <p>After amendment supra, NPPA fixed few meetings and few manufacturers demonstrated packs of different forms of different glass and non-glass with special features.</p> <p>NPPA was gracious to fix higher ceiling price for PVC and non-PVC under para 11(3) of DPCO, 2013 as per S.O. 1993(e) dated 03.06.2016 &amp; glass and non-glass with special features as per S.O. 2210(E) dated 24.06.2016 for 8 products and 8 manufacturers. The said S.O. also did not contain product "Ringer Lactate Injection IP".</p>	<p>NPPA fixed ceiling price of <b>Ringer Lactate Injection</b> 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 B Braun itself. 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. 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 also 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 B Braun Medical 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>As per S.O. 2209(E) dated 24.06.2016, NPPA fixed ceiling price of “Glass” and “non-Glass with special feature”. Incidentally, this S.O. also do not cover product Ringer Lactate Injection.</p> <p><b><u>Grounds of review application:-</u></b></p> <p>Review order 31015/9/2015-PI-I dated 05.05.2016 was having 1 review application dated 28.10.2013 filed against S.O. 2863(E) dated 20.09.2013. The said application was disposed off with a direction to examine in the light of S.O. 1192(E) dated 22.03.2016. Thus, NPPA was expected to review ceiling price under para 11(3) of DPCO, 2013, to fix separate ceiling price for “special packaging” BUT not for packaging for which ceiling price was fixed. NPPA did not do so, while revising ceiling price under S.O. 2401(E) dated 28.07.2017.</p> <p>As per S.O. 1993(e) dated 03.06.2016, NPPA notified prices of various I.V. fluids based on packagings, various packaging and special features mentioned in the Note “E” of the said notification.</p> <p>NPPA issued fresh notification 2210(E) dated 24.06.2016, re-fixing the prices of various I.V. fluids including Ecoflac plus self collapsible closed system infusion containers. The said notification was set aside by your office vide order dated 19.09.2016 after company filed a review application dated 13.07.2016.</p> <p>S.O. 2401(E) dated 28.07.2017 has only 4 packs of Ringer Lactate Injection IP – 100ml/250ml/500ml/1000ml. All these packs were covered under 1 S.O. as well earlier. There is no mention of type of packaging in the S.O. 2401(E) dated 28.07.2017. Had NPPA fixed ceiling prices for glass/PVC and non-PVC/glass and non-glass with special features, we could have understood that NPPA have considered “type of packaging” and fixed ceiling price in compliance of review</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>
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	<p>order 31015/9/2015-PI-I dated 05.05.2016. But there appears unilateral revision in ceiling price in the guise of para 11(3) of DPCO, 2013, which otherwise, not available under para 16 of DPCO, 2013.</p> <p>On perusal of working sheet, NPPA OM no. 8(34)/2016/DP/NPPA/Div.II dated 16.06.2017, considered by NPPA for fixing the ceiling price, company noticed that NPPA has considered price under DPCO, 1995. When ceiling price had been notified under DPCO, 2013, vide S.O. 2863(E) dated 20.09.2013, then it is difficult to justify the earlier revised ceiling prices under DPCO, 1995 or ceiling price of 2011.</p> <p>Ceiling price exercise vide S.O. 2401(E) dated 28.07.2017 is against the direction of OM of DOP of GOI dated 20.04.2017 under file reference 31026/31/2016-PI.I (pt-IV) which reads – “we direct NPPA not to review ceiling price before 5 years as well as against para 16 of DPCO, 2013, the same permit NPPA to revise ceiling price after 5 years from date of S.O. no. 2863(E) dated 20.09.2013 but not before 20.09.2018.</p>	
		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.

4. During the personal hearing, the representative of the Company submitted the following additional submission :-

1. **Packaging** - Since ceiling prices of several other IV fluids have been fixed in respect of various variants by NPPA, one of which one is 'type of Packaging' as per S.O. 1192(E) dt. 22.03.2016, NPPA amended para 11 by inserting 2 sub paras. As per sub para 11(3) of the DPCO 2013, prices for Ringer Lactate should also be fixed based on differential packaging.
2. **Safety/Special features** – NLEM 2015, (DPCO Amendment Order 2016) Section-29 (5) refers to **IV Fluids and solutions used for correcting water, electrolyte disturbances and acid-base disturbances** – as for eg. Sodium Chloride, Glucose + Sodium Chloride, Glucose 5%, Glucose 10% and also **Ringer Lactate**. Also to be noted is the issuance of notification by NPPA vide S.O.1993(E) dated 03.06.2016

and S.O. 2210(E) dated 24.06.2016; there is a clear differentiation and price ceiling accorded in the category of '**Non glass with special features**' for our **Ecoflac plus self collapsible closed system infusion containers** pertaining to - Sodium Chloride, Glucose + Sodium Chloride and Glucose 5%. The packaging/presentation of our Ringer Lactate is available in the same category of '**Non glass with special features**' which is **Ecoflac plus self collapsible closed system infusion containers** and offers the same safety benefits and special features, acknowledged earlier. Hence, the ceiling prices for Ringer Lactate should be differentiated as per the same category.

#### 5. **Examination:**

The company has submitted that the ceiling price fixed by NPPA for Ringer Lactate Injection vide SO 2401(E), dated 28.07.2017 is made applicable to any of the packaging which includes glass/PVC and non-PVC/glass and non-glass with special features. Company further stated that their product Ringer Lactate is available in the category of '**Non glass with special features**' which is **Ecoflac plus self collapsible closed system infusion containers** and offers the safety benefits and special features. Hence, the ceiling prices for Ringer Lactate should be differentiated and separate pricing should be fixed based on type of packaging.

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 5<sup>th</sup> 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 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 21<sup>st</sup> day of March, 2018.

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

To

1. M/s B.Braun Medical (India) Pvt. Limited,  
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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