

**No. 31015/79/2017-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 Otsuka Pharmaceutical 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 18.08.2017
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 21.11.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Otsuka Pharmaceutical 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) Followings are the Ceiling Price fixed by NPPA vide aforesaid Notification applicable to any of the packaging which include USP type II Glass Bottles / LDPE - FFS bottle, PP - BFS bottle Special features packaging like PVC/Non PVC Bag and Euro-head bottles.

Sl No	Name of Scheduled Formulation with Strength	Unit / pack size	After GST Notified Ceiling price as on 30/6/2017 0.10868/ml	Ceiling Price Vide Notification No. 2401 dated 28 th July, 2017
1	Ringer Lactate Injection	100 ml	10.87	18.95
2	Ringer Lactate Injection	250 ml	27.17	32.31
3	Ringer Lactate Injection	500 ml	54.34	41.17
4	Ringer Lactate Injection	1000 ml	108.68	72.38

(ii) Ceiling price of Ringer Lactate Injection I.P. first time was fixed vide S.O. No. 2863(E) dated 20/9/2013 @0.10 per ml applicable for all kind of packaging containers including Special Pack features.

(iii) NPPA revised Ceiling price for the said produce vide S.O. No. 1156(E) dated 28/4/2014 @ 0.11 per ml again it is for ail kind of packaging containers including Special Pack features.

(iv) As per S.O. 1192(E) dated 22/3/2016 NPPA have amended Para 11 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".

(v) NPPA fixed higher ceiling price for Special features pack like PVC/Non PVC Bag and Euro-head under para 13 (3) of DPCO 2013 as per S.O. 2210 (E) dated 24/6/2016 for three products with different volumes for particular manufacturers including Otsuka Pharmaceutical. The said S.O. did not contain the product Ringer Lactate Injection in question.

(vi) S.O. No. 2401(E) dated 28/7/2017 has only 4 volume packs of Ringer Lactate Injection I.P. 100ml/250ml/500ml and 1000ml. All these volume packs were covered under one Notification as well earlier. There is no mention of "Type of packaging" in the said S.O. NPPA has not considered the "Special features Packs" while fixing the price for Ringer Lactate Injection dated 28th July, 2017.

(vii) As per NPPA's O.M. No. 8 (35)/ 2016/ DP/ NPPA/ Div. II dated 16/6/2016, 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. Whereas, ceiling price had been notified under DPCO 2013, vide S.O. 2863(E) dated 20th September, 2013, there is no logic to either compare ceiling price under DPCO 1995 or consider ceiling price of 2011, in view of direction as per Office Memorandum of DOP, GOI dated 20/4/2017 vide file reference No. 31026/31/2016 - 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.

(viii) The working sheets for 1000ml of the said formulation in question contain application of recommendation of "Pronab Sen". Recommendation of Pronab Sen committee had not been notified under DPCO 2013.

(ix) Company confirmed having complied Para 31 of DPCO 2013 by submitting Price List in Form No. V and also commenced Production of the said formulation Ringer Lactate Injection I.P. vide First Batch No. 1171660 Mfgd. Date August, 2017 - 500 ml & Batch No. 1171652 Mfgd. Date August, 2017 - 1000 ml.

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

(a) Sr, No. 15 to 18 of the S.O. No, 2401 (E) dated 28th July, 2017 may kindly be withdrawn, OR

(b) Higher Ceiling Price for "Special Features Packs" (PVC/Non PVC Bag & Euro Head) may kindly be fixed separately for Ringer Lactate injection like it was done under S.O. No. 2210 (E) dated 24/6/2016 for Dextrose 5% Injection (5D), Sodium Chloride Injection 0.9% (NS) & Dextrose 5% with 0.9% Sodium Chloride Injection (DNS).

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 Ringer Lactate Injection vide S.O. 2863(E) dated 20.09.2013 for all kinds of packaging containers and the same was revised to 0.11/ml vide S.O. 1156(E) dated 28.04.2014. As per para 11(3) of DPCO, 2013 NPPA has been authorized to fix separate ceiling price in respect of various types of packaging and NPPA vide S.O. 2210(E) dated 24.06.2016 fixed separate ceiling price considering special feature pack like PVC/Non-PVC in case of IV Fluids. NPPA has not considered special feature pack while fixing the ceiling price of Ringer Lactate Injection dated 28.07.2017.</p>	<p>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 B Braun. 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 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. Otsuka Pharmaceuticals 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</p>

	<p>Company is of the opinion that NPPA has considered price under DPCO 1995 whereas ceiling price has been notified under DPCO 2013 vide SO 2863(E) dated 20.09.2013.</p> <p>Company has also stated that fixation of ceiling price for Ringer Lactate Injection vide S.O. 2401(E) dated 28.07.2017 is against the direction of OM (ref. no. 31026/31/2016-PI(Pt-IV) of DOP dated 20.04.2017).</p>	<p>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>The products are not appearing in the Pharmatrac.</p>

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 made the following further submissions –

- 1 Ceiling price of Ringer Lactate Injection I.P. first time was fixed vide S.O. No. 2863(E) dated 20/9/2013 @0.10 per ml and subsequent revisions were applicable for all kind of packaging containers including special pack futures like PVC/Non PVC Bag and Euro Head bottles.
- 2 The recent price reduction vide said notification for Ringer Lactate Injection is not viable to manufacture the product in Special Pack features (PVC/Non PVC Bag and Euro Head bottles)
- 3 As NPPA fixed higher ceiling price for Special features pack like PVC/Non PVC Bag and Euro-head under para 13(3) of DPCO 2013 as per S.O.2210(E) dated 24/6/2016 for three products (5D, NS & DNS) with different volumes for particular manufacturers including Otsuka Pharmaceutical. The latest revised said S.O. did not contain the product Ringer Lactate Injection in Question.

Company requested for separate higher price notification for Ringer Lactate Injection in PVC/Non PVC Bag and Euro Head bottles with different volumes.

4.2 NPPA representative submitted that they have no further comments in addition to as stated above.

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 USP type II Glass Bottles/LDPE - FFS bottles, PP BFS bottles Special features packaging like PVC pouches/Euro Head. Company requested for separate pricing 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 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 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 Otsuka Pharmaceutical India Private Limited,
21st Floor, West Gate, Tower B, Nr. YMCA Club,
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2. The Member Secretary,
National Pharmaceutical Pricing Authority,
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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