

No. 31015/76/2017-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 Albert David 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 02.08.2017
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 26.12.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Albert David 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:-

a. The present Application is being filed seeking **review** and withdrawal of S.No.15 to 18 of the S.O. No. 2401 (E) dated 28.07.2017, whereby NPPA has fixed and made it applicable to any of the packaging which includes USP type II Glass Bottles/LDPE FFS bottles/PP BFS bottles/PVC pouches/Euro Head.

b. Company explained how NPPA fixed ceiling price of Ringer Lactate Injection under DPCO 2013 & revised it in contravention to provisions of DPCO 2013:-

(1) Ceiling price of Ringer Lactate Injection I.P. was fixed vide S.O. no. 2863(E) dt. 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).

(2) 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 Poly(LDPE).

(3) 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,NPPA has been authorized to fix separate ceiling rice in respect of various variants, of which one is ‘type of Packaging’.

(4) After amendment supra, NPPA fixed few meetings and few manufacturers demonstrated packs of ‘Euro-head’.

(5) NPPA fixed higher ceiling price for 'Euro-head' under para 11(3) of DPCO 2013 as per S.O. 2210(E) dt. 24/06/2016—for 8 products and for 8 manufacturers. The said S.O. did not contain product 'Ringer Lactate Injection I.P.

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

Grounds of Review Application

(7) 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.

(8) 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 1 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, the 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.

(9) 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; 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.

(10) The working sheets for 1000ml contains application of recommendation of Pronab Sen. Recommendation of Pronab Sen committee had not been notified under DPCO, 2013, lacks legal backing. Therefore, according to our understanding, revision of price for any pack size i.e. 100ml/250ml/500ml/1000ml is void *ab initio*.

(11) As per para 16 of the DPCO 2013, NPPA can revise price after 5 years from date of S.O. no. 2863(E){dt. 20/09/2013} but not before 20/09/2018. Accordingly, Company found that NPPA has exercised powers not vested under DPCO 2013 under para 16 BUT arbitrary revised price on 28/07/2017, for all packs, contrary to DPCO 2013.

c. In the light of the above, company prayed as under:-

1. Sr. no. 15, 16, 17 & 18 of the S.O. dt. 28st July 2017, be withdrawn immediately;
2. Ceiling price for different type of packs be fixed separately for Euro heads packs, without tinkering ceiling price for other packs.

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:-

Company's Grievances	NPPA's comments
<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 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. This price was also for any pack-Glass or Poly (LDPE).</p> <p>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. NPPA was gracious to fix higher ceiling price for "Euro-Head" under para 11 (3) of DPCO, 2013 as per S.O. 2210 (E) dated 24.06.2016- for 8 products and for 8 manufacturers. <u>The said S.O. did not contain product "Ringer Lactate Injection".</u></p> <p>As per S.O. 2209 (E) dated 24.06.2016, NPPA fixed ceiling price of "Glass" and "non-Glass". <u>Incidentally, this S.O. also do not cover product "Ringer Lactate Injection".</u></p> <p>Company has pointed out that DOP vide review order no. 31015/09/2015-PI.I dated 05.05.2016 directed NPPA to examine the case of I.V fluids price fixation in the light of S.O. 1192(E) dated 22.03.2016. Thus, NPPA was expected to review ceiling price under</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 5.05.2016 against the review filed by M/s. B Braun. DOP vide review order no. 31015/9/2015-PI.I dated 5.05.2016 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. Albert David 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>para 11(3) of DPCO, 2013 to fix separate ceiling price for special packaging but NPPA did not do so while revising ceiling price under S.O. 2401 (E) dated 28.07.2016. Vide S.O. 2401(E) dated 28.07.2016, NPPA covered only 4 packs of Ringer Lactate injection i.e. 100 ml, 250 ml, 500 ml & 1000 ml without differentiating type of packaging viz. Glass/ Non-PVC/Non-Glass special feature.</p>	
<p>Company has also pointed out that as per draft working sheet of NPPA's OM 8 (34) /2016/DP/NPPA/Div.II dated 16.06.2017; they have noticed that NPPA has fixed ceiling price considering the provisions of DPCO, 1995. Company has also stated that NPPA has violated the direction of DOP issued under file reference 31026/31/2016/PI-I (Pt.-4) by revising the price of subject formulation before 5 years. As per company opinion, NPPA has applied the recommendation of Pronab Sen committee while fixing the ceiling price for 1000 ml pack of this 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>

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 stated that –

(1) It is incorrect to say that product Ringer Lactate I.P. was new entrant in NLEM 2015. RL was in Schedule I of DPCO 2013 and accordingly NPPA fixed ceiling price 1st

time as per S.O. 2863(E) dt. 20/09/2013. NLEM 2015 neither removed product RL nor added it. Therefore, it is incorrect to assume that NLEM 2015 was revised - so far as product RL is concerned.

(2) As per para 17 (1) of the DPCO 2013, ceiling price of Product RL cannot be changed due to revision in NLEM 2015. Product RL was in schedule I of the DPCO 2013 (NLEM 2011/2013) and it remains as is in NLEM 2015. Therefore, it will be a dangerous proposal to conclude that there is change in NLEM 2011---so far as product RL is concerned. Para 17(1) of DPCO 2013 reads "*A decisionand thereafter, the ceiling price(s) for the medicine(s) added in the first schedule shall be fixed as per the provisions of this order with in a period of sixty days from the date of notification.*" DPCO 2013 recognizes only additions to NLEM as change.

(3) In fact, NPPA did not revise ceiling price in 2015 or in 2016 or till 31/07/2017. Had product RL was an addition, NPPA would have an obligation to revise price within 60 days. It cannot be concluded that 60 days completed on 28/07/2017 from issue of NLEM 2015. This action of NPPA alone suggest that NPPA erred in understanding true meaning of para 17(1) of the DPCO 2013 to conclude now that ceiling price revision was due because of Revision in NLEM in 2015.

(4) As stated in para (3) of review application, NPPA amended para (11) of DPCO 2013, vide S.O. 1192(E) dt. 22/03/2016, NPPA empowered to revise price of any drug--on the basis of (i) specific therapeutic rationale OR (ii) considering the type of packaging OR (iii) pack size or But presently S.O. 2401(E) dt. 31/07/2017 does not address any of the forgoing factor either combined or in isolation. Earlier price was on the basis of per ml basis--which could determine price of either 500ml or 1000ml or any other pack. Therefore, it is incorrect to conclude that NPPA revised price on the strength of para 11(3) of the DPCO 2013--as directed in review order no. 31015/9/2015-PI.I, dt. 05/05/2016 in the matter of M/s B.Braun Medical (India) Pvt. Ltd. NPPA's representative fairly admitted during PH that whiling revising price of RL on 28/07/2017, NPPA this time did not consider packaging material---either glass OR plastic OR non-PVC with special features. Thus present revision is not under para 11(3) of DPCO 2013.

(5) NPPA is not collecting data from several IV Fluid manufacturers who were granted mfg. License from none other than **DOP, GOI**. During PH, a glass bottle of product RL --B.no. G17090559, mfg. dt. 09/2017; DL no. 02/LVP/SC/P of 2016 manufactured by m/s Vision Parental Pvt. Ltd, Gorakhpur (U.P.) was produced bearing MRP Rs. 60.86 as against MRP of Rs.46.11. Company informed earlier similar practice in the case of review application against **Dextrose 10%**. Responsibility to grant mfg. DL in the case of IV Fluid is of DOP, GOI; monitoring of ceiling price is also under DOP, GOI. Thus many IV Fluid mfgers. are not adhering to ceiling price NOR registered under IPDMS. Such mfgers. supply to AIIMS, various govt. hospitals, and sale in retail market. It is incorrect to revise price on the basis of incomplete data.

(6) Thus both arguments of NPPA--(I) Revision in NLEM in 2015; (II) Due to review order 31015/9/2015-PI.I. dt. 05/05/2016 in view of addition of para 11(3) of the DPCO 2013 are not maintainable.

(7) Company requested to consider arguments submitted as per review application dt.03/08/2017 and to quash item S.no.15 to 18 of S.O. 2401(E) dt.28/07/2017.

5. In reply, NPPA representative submitted no further comments.

6. Examination:

Company has pointed out that DOP vide review order no. 31015/09/2015-PI.I dated 05.05.2016 directed NPPA to examine the case of I.V fluids price fixation 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 NPPA did not do so while revising ceiling price under S.O. 2401 (E) dated 28.07.2017. Company further stated that NPPA, vide S.O. 2401 (E) dated 28.07.2017, covered only 4 packs of Ringer Lactate injection i.e. 100ml, 250ml, 500ml & 1000ml without differentiating type of packaging viz. Glass/ Non-PVC/Non-Glass special feature.

6.2 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.

6.3 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.”

6.4 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.

6.5 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.

6.6 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.

6.7 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.

6.8 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.

6.9 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 / Sodium Chloride, but did not contain 'Ringer Lactate Injection', which is also in the category of IV Fluid.

6.10 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.

6.11 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.

7. **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 Albert David Limited,
B-12&13, Meerut Road, Industrial Area,
Ghaziabad-201003.
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