No. 31015/63/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: **Review application of M/s B.Braun Medical (India) Pvt. Ltd. against price fixation of "Ecoflac Plus Self Collasible Closed System Infusion Containers" vide NPPA order No. S.O. 2210(E) dated 24.6.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

Ref: **1) Review application received in DoP on 13.07.2016**
2) NPPA notification under review S.O. No.2210(E) dated 24.6.2016
3) Record Note of discussions held in the personal hearing held in the matter on 28.7.2016.

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. Ltd. (hereinafter called the petitioner) against notification S.O. No.2210(E) dated 24.6.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Ecoflac Plus Self Collasible Closed System Infusion Containers.

2. The petitioner has contended as under:

I. Further to amendment of DPCO 2013 para 11(3), NPPA notified ceiling prices for Glucose 5% injection, Sodium Chloride 0.9% Injection and Glucose 5% Injection and Sodium Chloride 0.9% Injection vide Order S.O. 1993 (E) dated 3rd June 2016 based on packing, various packaging and special features mentioned in the Note 'E' of the said notification.

II. NPPA issued fresh notification S.O. 2210(E) dated 24th June, 2016 refixing the prices of various IV Fluids. Said Notification has clubbed our products Ecoflac Plus Self Collapsible Closed System Containers with other products **which are not comparable to those of B. Braun on therapeutic and clinical rationale.**

III. Company further submitted that the unique features of Ecoflac Plus Self Collapsible Closed System Infusion Containers which are different from other companies cited in the S.O. 2210(E), **showing therapeutic superiority of the Ecoflac Plus over the products of such other companies'.**

(i) **<u>Ideal Uniform Self Collapsibility</u>.** When administered through a gravity infusion non vented IV set, they do not need any additional venting for determined flow of the IV Solution into the patient's vein. The therapeutic implication of this property is that it delivers exact dose per minute to the patient's blood stream. **Ecoflac Plus demonstrate this property but in contrast, the products of Albert David, Dennis, Amantas and Aculife does not demonstrate this property for any of their pack variations**

(ii) **<u>logarithmic volume measurement for infused volume</u>**: The volume of administered infusion can be measured any time during the administration. There is a need to administer only part of the drug as per dosage calculated per kg of body weight, mainly used on chemotherapy, blood glucose management and ionotropic drugs used in cardiac emergencies. **Ecoflac Plus Closed System Infusion Containers have logarithmic volume measurement, which allows a flexibility to stop the drug administration any time. The uniform collapsibility behavior of Ecoflac Plus Self Collapsible Closed System Containers is attached as a video. No other self collapsible product of any other manufacturer demonstrate this property**

(iii) **<u>No Exchange of Hazardous Contaminants with Environment</u>:** self collapsible, closed system device should not exchange air or hazardous contaminants (Oncology Drugs Etc) of/ with the adjacent environment. The Exchange of air with environment is mechanically prohibited. **Ecoflac Plus Self Collapsible Closed System Containers do not exchange any air / hazardous contaminants with the adjacent environment.** All those products not complying with self collapsibility will not have this property as mentioned in (i).

(iv) **<u>Residual Volume in Container</u>**: Once the container is fully emptied, the residual solution in the container of a self collapsible closed system infusion should not be more than 7ml. **Ecoflac Plus Self Collapsible Closed System Containers have this property and the product validation report proves the same. Whereas the products of Albert David, Dennis, Amantas and Aculife do not demonstrate this property.**

(v) **<u>No Suck Back in the container</u>:** Even if the System is left in the vein of the patient after solution in the container has completely emptied, there should not be any suck back due to development of partial vacuum in the IV system. This is for patient safety since if the IV System is not self collapsible, patient's venous blood can get sucked into the IV channel leading to blood loss and possibility of infection. **Ecoflac Plus Self Collapsible Closed System Containers does not show any suck back. Whereas the products of Albert David, Dennis, Amantas and Aculife does not demonstrate this property.**

(vi) **<u>No Contamination during Admixing</u> :** Ecoflac Plus is the only container which allows needle free drug mixture thereby eliminating the risk of exposure of hazardous drugs like Neoplastic Drugs or Harmones to the healthcare workers. They also provide **a video showing needle free admixture for reference. No other product demonstrate this property.**

(vii) **Drug Compatibility:** Ecoflac Plus Closed System is compatible with all the known forms of drugs which are required to be admixed for infusion**. Company provides a data access card to hospitals which gives them rights to access the compatibility data of various known drugs with the container systems. This compatibility is very critical for stability of drugs admixed in Infusion since many a drugs reacts with other container materials and show a degradation to the extent of > 10% in 1 hour compromising the clinical outcome of the patient. PVC bags are not compatible with many drugs including Oncology and ionotropes.**

IV. Company further submitted that as per the above features, Ecoflac Plus Self Collapsible Closed System Infusions Containers confirms to the definition of "Closed System Devices" which states "A closed system drug transfer device is a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system. (Ref. National Institute of Occupational Safety and Health, Centre for Disease Control & Prevention (CDC) within the U.S. Department of Health and Human Services).

V. They further submitted that the working sheets in relation to S.O. No. 2210 (E) were uploaded by the NPPA on July 28, 2016. A preliminary review of these reveal that there are several critical errors therein stated as under:-

a. Viaflex Bag 100ml Sodium Chloride 0.9% is shown as having a PTR of Rs.12.00, which is incorrect.

b. Pronab Sen Committee report's method of calculation cannot be applied in the case of 100ml packs with special features and 250ml packs with special features since, neither this report was accepted in totality nor this is valid in this case as the method of calculation as per this report is applicable for different strengths whereas Sod Chloride 0.9% is same strength but different packs.

VI. They submitted that while fixing and calculating the ceiling price, S.O. No. 2210 (E) clubs ECOFLAC PLUS with the products of other manufacturers which do not exhibit the same therapeutic benefits. This is arbitrary and discriminatory and cannot stand the test of reasonable classification under Article 14 of the Constitution of India.

VII. They requested this Department:-

(i) **To issue a separate ceiling price for ECOFLAC PLUS closed system infusion under amended para 11(3) of DPCO 2013 since Ecoflac Plus Closed System offers a specific and unique therapeutic benefit and delivers added clinical and safety benefits to patients.**

(ii) **Till the disposal of the present review petition, to permit B Braun Medical (India) Private Limited to sell ECOFLAC PLUS closed system as per the ceiling prices prescribed by SO.1993 (E) dated 3rd June 2016.**

Comments of NPPA:

1. The reply to the review petition on merit basis is as follows:-

2. Para 1 and 2 of the company:-

The content of para 1 & 2 are for information only and don't require any comment.

3. In para 3(1) to 3(8), there is no specific prayer asked by the petitioner. The features of the product have already been examined by the Authority.

4. Refer para 3(9)(a), letter has been issued to M/s Baxter regarding the PTR and MAT value of Implementation of 100 Viaflex Sodium Chloride 0.9% solution.

5. Refer para 3(9)(b), the ceiling price for 100ml specific pack is fixed by NPPA by deriving from the existing ceiling price under the common principle adopted by Committee of Experts of Pharmacoeconomics duly approved by the Authority. The manufacturers were selling this product as "without price approval". Hence decision taken by NPPA is correct and in consumer interest.

3. In the personal hearing held on 28th July, 2016, the company further submitted its plea as under:

1. For point no 3(i) Ideal self collapsibility, company made a demonstration during the hearing with its Ecoflac Plus self collapsible closed system container, One container from a company Amantas (100ml) which is approved for special feature and one bottle of Eurohead (some other Indian manufacturer not reflecting in the notification no 2210(E). The infusion delivery was set up with a non vented IV set and the set was attached to IV canula. The roller was opened and infusion demo was set on an IV Stand. Only Ecoflac Plus bottle completely collapsed releasing complete solution out of the bottle. Other two bottles, One Steriport of Amanta and Eurohead of (some other Indian manufacturer not reflecting in the notification no 2210(E), almost 70ml of the solution was left in the bottle proving that these bottles were not self collapsible.
2. Importance of self collapsibility to avoid contamination during infusion delivery was explained members of the department. A presentation of Risk Management in Infusion therapy and qualification of Ecoflac Plus was presented for further reference. The contamination of the solution in vented containers was informed one such report was submitted, which was development of Micro contamination during infusion in vented containers where as ideally self collapsible containers do not cause any contamination during infusion delivery, which was also reflected in the report.
3. A demonstration on Safe and Needle Free Admixture was given to the department and need for safe and needle free admixture explained for the safety of the patient and healthcare worker.
4. Logarithmic Volume measurement during infusion was explained and shown how Ecoflac Plus demonstrate this property which no other product in the market can demonstrate. Need for volume measurement during infusion of drug and solution is explained where it was informed that many drugs dosage is based on the per

kg body weight, and to deliver exact dosage how Ecoflac Plus allows doctor to stop the infusion at desirable level by checking the volume delivered by the bottle.

5. Drug compatibility of Ecoflac Plus was brought to the notice of members. A complete detail of this feature has been attached with review application. It was shown how some of the critical drugs would degrade in PVC containers over time. Data of such products was submitted along with risk management presentation.
6. It was also informed to the members that Eurohead bottles of Albert David, Nirma and Claris are not available in the market and as per information available with the company, these companies were not marketing these products In India during the last 3 years. Also it was informed that Eurohead products of Claris, Nirma and Albert David and Steriport Bottles of Aamanta do not demonstrate ideal self collapsible properties and their solutions cannot be infused 100% without venting.
7. One sample invoice of Viaflex Sod Chloride 100ml with higher MRP was shown during the meeting.
8. Ecoflac Plus container has a ergonomic structure and behaves as bottle bag. This takes care of all the risks associated with preparation of Infusion in bag i.e. perforation of bag during admixture and spiking. Since Ecoflac Plus is standiform, it makes admixture and infusion preparation risk free and behaves like a bag (Ideal Self Collapsibility) during infusion.
9. It was informed that due to ideal self collapsibility, Ecoflac Plus does not cause any suck back of blood in the infusion line saving the risk of infection and other side effects to the patient.
10. Company requested that since Ecoflac Plus Self Collapsible Closed System Containers deliver all the features of safety to the healthcare, worker and patient and therefore helps in better clinical outcome. This should be treated as 'unique delivery system' and awarded separate price from the products mentioned in S.O.2210(E), dated 24th June, 2016, since four companies' products, namely, Amantas; Albert David; Denis; Aculife and Claris (Euro Head) do not have ideal self-collapsibility and lack many features which Ecoflac Plus demonstrates for safe infusion therapy.

NPPA Comments:

NPPA representative submitted that –

1. The authority has verified the special features of the products claimed by different companies those demonstrated before the Special Sitting of Authority on 21.6.2016. Separate ceiling price cannot be given on the basis of each feature separately to every company.
2. Letter has been issued to M/s Baxter regarding the PTR and MAT value of Implementation of 100 Viaflex Sodium Chloride 0.9% solution. The revision will be made on the basis of reply from M/s Baxter.

3. The ceiling price for 100ml specific pack is fixed by NPPA by deriving from the existing ceiling price under the common principle adopted by Committee of Experts of Pharmacoeconomics duly approved by the Authority. The manufacturers were selling this product as "without price approval". Hence decision taken by NPPA is correct and in consumer interest.

4. **Examination:**

4.1 It is seen that the NPPA has notified the prices of IV Fluids on 3.6.2016 in compliance of Government's Review Order dated 5.5.2016 vide SO NO.1993(E). Subsequently, NPPA once again, suo-motu, revised the prices of IV Fluid vide their SO No. 2210(E), dated 24.6.2016 without any specific and express powers under the DPCO to do so.

The provision under Para 18(i) of DPCO 2013 clearly stipulates that the revision of ceiling price shall be undertaken.

"as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier;"

In this particular case, **neither the NLEM has been revised by Ministry of Health & Family Welfare during the period from 3.6.2016 to 24.6.2016, nor there is a gap of five years from the date of fixing the ceiling price under NPPA's Order, dated 3.6.2016 nor is there any express order of the Government under any review petition to re-examine the ceiling price in question fixed vide NPPA order dated 3.6.2016.**

4.2 The basis of the 2nd suo-motu revision of IV Fluids vide NPPA SO No.2210(E), dated 24.6.2016 does not seem to be covered under DPCO 2013.

5. It is also noticed that the impugned suo-motu re-fixation of ceiling prices by NPPA, has been done in its Authority Meeting held on 23rd June, 2016, under modified categories of glass, non-glass and separate ceiling prices for specific manufacturers of non-glass with special features, without any consultation or recommendation of the Expert Committee set up under Para 11 (4) of DPCO

Therefore NPPA's SO No.2210(E) dated 24.06.2016 is liable to be set aside.

6. **Government Decision:**

In the light of the foregoing analysis, Impugned Order of the NPPA vide S.O. No.2210(E)dated 24.06.2016 is hereby set aside with immediate effect.

Issued on this date of 19th day of September, 2016.

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

To

1. **M/s. B.Braun Medical (India) Pvt. Ltd.**
   23A, 3rd Floor, Shivaji Marg,
   Najafgarh Road,
   New Delhi-110 015.
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**