

No. 31015/65/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s Parenteral Drugs (India) Limited against price fixation of their formulation "Glucose 10% injection" vide NPPA order No. S.O. 1688(E), dated 24.05.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 01.06.2017
2) NPPA notification under review S.O. No.1688(E), dated 24.05.2017

1. This is a review petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Parenteral Drugs (India) Limited (hereinafter called the petitioner) against notification S.O. No.1688(E), dated 24.05.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Glucose 10% injection.

2. The petitioner has contended as under:

- I. Price Notification Order provides for ceiling price of Glucose Injection 10% (500ml) of Rs.26.58, while the ceiling price of Glucose Injection 10% (1000ml) has been fixed at Rs.24.43, which needs review; as when the size of the pack increases the cost of the ingredients of the drug as well as the cost of packing material also increases proportionately.
- II. For ready reference, the example of the ceiling price fixed for Dextrose 5% may kindly be taken where for a pack of 500ml (non-glass) is Rs. 28.87 while ceiling price for pack of 1000ml (non-glass) has been fixed at Rs. 49.04 per bottle. Therefore Government needs to review the prices of Glucose Injection 10% 1000ml.
- III. NPPA while taking *Price to Retailer*, has considered only the price of PDIL for Glucose injection 10% 1000ml while there are number of manufacturers who manufacture Glucose Injection 10% in 500ml and 1000ml packs.
- IV. As regards the Price to Retailer value of the product manufactured by the company, during March and April 2015 Glucose Injection 10% 1000ml was sold by Parenteral Drugs India Limited at a price of Rs. 34.20 per bottle and therefore the PTR value of Rs.22 for the month of August 2015 is not as per actual which is leading to ceiling price at a lower level.
- V. In view of the above, Company prayed that the price notification S.O. 1688 (E) dated 24th May, 2017 may be reviewed as far as it provides for ceiling price of Glucose Injection 10% 1000ml.

3. Comments of NPPA:

- I. Ceiling price of **Glucose Injection 10%** was notified as Rs.26.58 for a pack size of 500 ml and Rs.24.43 for 1000 ml pack vide S.O. 1688(E) dated 24.03.2017 and the same was revised to Rs. 25.59 for a pack size of 500ml and Rs.23.43 for 1000 ml pack vide S.O. 2058 (E) dated 30.06.2017 under para 4, 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 **Glucose Injection 10%**. 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&2.	Company has stated that NPPA has fixed the ceiling price of Glucose Injection 10% (500 ml) as Rs.26.58 while the ceiling price of Glucose Injection 10% (1000 ml) has been fixed at Rs.24.43, which is not correct. As per company opinion, when the size of pack increases, the cost of the ingredients of the drugs as well as cost of packing material also increases proportionately. Company has stated that NPPA has fixed the ceiling price Rs.28.87 for Dextrose 5% in 500 ml pack and Rs. 49.04 for Dextrose 5% in 1000 ml pack.	NPPA fixed the ceiling price as Rs.26.58 for a pack size of 500 ml and Rs.24.43 for 1000 ml pack vide S.O. 1688(E) dated 24.03.2017 based on the data provided by AIOCD-AWACS, for the month of August, 2015. NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. M/s. Parenteral Drugs (India) Limited did not make any representation against the proposed ceiling price uploaded on NPPA's website.
3.	Company has also pointed out that NPPA has considered only the price of PDIL for working out the price of Glucose Injection 10%, 1000 ml while there are number of manufacturers who manufacture Glucose Injection 10 % in 500 ml & 1000 ml pack.	NPPA fixed the ceiling price as Rs.26.58 for a pack size of 500 ml and Rs. 24.43 for 1000 ml pack vide S.O. 1688(E) dated 24.03.2017 based on the data provided by AIOCD-AWACS, for the month of August, 2015. No company had made any representation against the proposed draft working sheet of proposed ceiling price uploaded by NPPA on its website.
4.	Company has also stated that they have sold Glucose Injection 10 % at a price of Rs. 34.20/bottle and therefore, PTR value Rs. 22.00 for the month of August, 2015 taken by NPPA is not actual.	NPPA has fixed the ceiling price based on the data provided by AIOCD-AWACS, for the month of August, 2015.

- III. Company has not challenged any notification in respect of **Glucose Injection 10%** in the Court.

5. Examination:

On examination of calculation sheet of Glucose 10% 500 ml pack, it is seen that the price of the formulation was fixed under para 4(1) of DPCO by considering the PTR of five companies, whose MAT value was more than 1%, and the price fixation is in order.

5.2 As regards price fixation of Glucose 10% 1000 ml pack, it is observed from the calculation sheet (page 24/c) that as there was no other competitor, the ceiling price was fixed under para 4 and 6 of DPCO, 2013, by applying reduction under monopoly condition. The claim of the company that there are other companies who are also manufacturing 1000ml pack, cannot be accepted, as company did not submit any documentary proof in support of its claim. NPPA fixed the ceiling price of the subject formulation by considering Pharmatrac data for the month of August, 2015, as per provisions of DPCO, 2013. However, the company claimed that the PTR of Dextrose 10% Infusion 1000ml, being manufactured by the company, was Rs.34.20 as on August, 2015, (and not Rs.22.00 per pack considered by NPPA). In support of its claim, the company submitted a photocopy of invoice as documentary proof. In view of this, NPPA may be directed to examine the information/documentary proof submitted by the petitioner about the actual PTR of the company's product Dextrose 10% Infusion 1000ml pack, and after verification, re-fix / revise the ceiling price of Glucose 10% injection 1000ml pack, on merit.

6. Government decision:

“NPPA is hereby directed to examine the information/documentary proof submitted by the petitioner about the actual PTR of the company's product Dextrose 10% Infusion 1000ml pack, and after verification, re-fix / revise the ceiling price of Glucose 10% injection 1000ml pack, on merit.”

Issued on this date of 1st day of January, 2018.

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

To

1. M/s. Parenteral Drugs (India) Limited,
340, Laxmi Plaza, Laxmi Industrial Estate,
New Link Road,
Andheri (West),
Mumbai-400 053.

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**