

No. 31015/67/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s Parenteral Drugs (India) Ltd. against notification No. S.O. 3131 (E) dated 10.12.2014 for fixing ceiling price of Glucose injection 10% and SO No. 3134(E) dated 10.12.2014 fixing ceiling price of scheduled medicine "Mannitol 20% 100 ml under para 31 of DPCO 2013. issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 12.12.2014
2) NPPA notification under review S.O. No. 3131 (E) dated 10.12.2014 and SO No. 3134(E) dated 10.12.2014
3) Record Note of discussions held in the personal hearing held in the matter on 25.2.2015

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation notification No. S.O. 3131 (E) dated 10.12.2014 for fixing ceiling price of Glucose injection 10% and SO No. 3134(E) dated 10.12.2014 fixing ceiling price of scheduled medicine "Mannitol 20% 100 ml" fixed/revised ceiling price under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/s Parenteral Drugs (India) Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 12.12.2014 under para.31 of DPCO, 2013 for the review of NPPA Price notification No. S.O. 3131 (E) dated 10.12.2014 for fixing ceiling price of Glucose injection 10% and SO No. 3134(E) dated 10.12.2014 fixing ceiling price of scheduled medicine "Mannitol 20% 100 ml" under DPCO, 2013 included in Schedule-I of the order.

3. The grievance of the Petitioner raised in their review application dated 12.12.2014 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the Record Note of discussions held in the review hearing on 25.2.2015. Record Note of discussion is made integral part of the review order. After considering the comments of NPPA, the Petitioner has raised the following points, on which comments given by NPPA representative, during the hearing and Government's comments on the issue is recorded subsequently on each point:

Petitioner's submission during personal hearing

The petitioner representative submitted invoices of December 2014 pertaining to Mannitol Injection 20% in 100 ml and Dextrose 10% 500 ml having MRPs Rs.38.85 per btl for

Mannitol 20% and Rs.26.25 per btl for dextrose 10%.The MRPs are same as per the invoices of November 2014 and October 2014.

The petitioner representative mentioned that in the case of Dextrose 10% before notification No. SO No. 1819(E) dt.21.6.2013 the MRP was Rs. 73.50 for 500 ml . After coming into force of SO No. 1819 (E) dt. 21.6.2013 they have reduced the MRP to Rs. 26.25 for Dextrose 10%. The ceiling price of Dextrose 10% was increased vide SO No. 3131 (E) dt. 10.12.2014. The ceiling price was notified Rs.0.05316 per ml.

The petitioner representative mentioned that as per clause (d) under the notification SO 3134(E) pertaining to Mannitol injection the MRP for the new manufacturer is Rs. 57.75 which is a big increase for the new manufacturer. However, the company whose MRP earlier was Rs. 38.85 cannot increase it under para 13(2) of DPCO 2013 as mentioned in note (d) under the notification. Similarly for Dextrose 10% though they cannot increase the price from their MRP Rs.26.25 and the new manufacturer can launch the product at Rs.27.91 MRP per btl. The petitioner representative mentioned that this is a very competitive market for IV fluids and the higher MRP is always preferred by the retailers in the hospitals/nursing homes. They are, thus, finding it very difficult to sell their products at lower MRP.

PTR for Glucose Injection 10% was Rs.13.00 and Rs.22.00 for 500 and 1000 ml respectively during May 2012. For Mannitol 20%, during May 2012, PTR was Rs.24.00 for 100 ml. Invoices are also submitted for same.

NPPA comments:

NPPA representative stated that the PTR of May 2012 for the purpose of price fixation of Dextrose 10% of M/s Parenteral Drugs were Rs.9.25 and Rs.16.75 for 500 ml and 1000 ml respectively. The same figure has been considered in working out the price relevant for 10th December 2014 notification. The only change that has been made is in respect of providing WPI for implementing DOP orders. Thus in current notification only WPI has been changed and which can only be the subject matter of review under para 31 of DPCO 2013. The PTRs of Mannitol 20% that were considered in the working were Rs. 20 and Rs.50 for 100 ml and 300ml respectively. As per para 13 of DPCO, 2013, all the existing manufacturers of scheduled formulations, selling formulations at price higher than ceiling price (plus local taxes as applicable) notified by Government are required to revise their prices downward and existing manufactures selling below the ceiling price notified by the Government shall maintain their existing price. Thus, a manufacturer is not permitted to carry out upward revision in price. The petitioner shall follow the provisions of DPCO, 2013.

Department's comments:

The petitioner representative mentioned that as per notification SO No. 3134 (E) dt. 10.12.2014 pertaining to Mannitol injection 20% the MRP for the new manufacturer is Rs.57.75 which is a big increase for the new manufacturer. As per note (d) of the said notification the existing manufacturers cannot increase their previous price upto ceiling price level. Similarly for Dextrose 10% though they cannot increase the price upto the ceiling price fixed vide SO No. 3131(E) dt. 10.12.2014 but the new manufacturer can launch the new product at the ceiling price. As per the petitioner representative higher MRP is always preferred by the retailer in the hospitals/nursing homes.

In this connection it may be mentioned that there is specific provision contained in para 13(2) that the existing manufacturers selling the scheduled drug at a price lower than the ceiling price shall maintain their existing maximum retail price. Therefore, the company has no merit in this point.

5. Based on the above and other documents on record, the Government has decided as under:

“The points raised by the company have no merit and the review petition is, therefore, rejected. “

Issued on this date of 14th May, 2015

(A. K. Sah)
Under Secretary to the Govt. of India
For and on behalf of the President of India

To

1. M/s. Parenteral Drugs (India) Ltd.
340, Laxmi Plaza,
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New Link Road
Andheri (West), Mumai – 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. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information
3. TD, NIC for uploading the Order on the Department's website