

No. 31015/25/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, 3rd Floor, Janpath Bhavan, New Delhi

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

Subject: Review application of M/s. Magnet Labs Ltd. against fixation/revision of ceiling prices of “Ranitidine Oral Solution (5 ml. contains Ranitidine HCL eq. to Ranitidine 75 mg) vide NPPA notification S.O. No. 851(E) dated 25/3/2015 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 23.4.2015
2) NPPA notification under review S.O. No. 851(E) dated 25/3/2015
3) Record Note of discussions held in the personal hearing held in the matter on 16.6.2016.

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 851(E) dated 25/3/2015 fixed retail price of “Ranitidine Oral Solution (5 ml. contains Ranitidine HCL eq. to Ranitidine 75 mg) under DPCO, 2013 included in Schedule-I of the order.

2. And whereas aggrieved by the above notification, M/s Magnet Labs Ltd. submitted review application dated 23.04.2015 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 851(E) dated 25/3/2015.

3. The grievance of the Company raised in their review application dated 23.4.2015 were sent to NPPA and the comments of NPPA thereon were given to the Company through the Record Note of discussions held in the hearing on 18.6.2015. Record Note of discussion is made integral part of the review order. After considering the comments of NPPA the Company 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 against each point:

Company’s comment:-

4. The company representative mentioned that they were producing Ranitidine injection which is a scheduled formulation and they intend to launch Ranitidine Oral Solution and, therefore, they have approached NPPA for price fixation. The company representative mentioned that there is only one manufacturer i.e. M/s Hema Laboratories and marketed by M/s J.B. Chemicals which is producing the same drug under brand name Rantac Syrup. The company representative mentioned that the MRP of J.B. Chemicals is Rs. 69.50 for 100 ml while their price notified by NPPA is Rs.52 for 100ml (without local taxes). The company representative mentioned that the price is unfavourable to them.

5. The other point raised by the company was that M/s J.B. Chemicals has launched another pack of the same product with same strength i.e. 30 ml. with a MRP of Rs.38. However, if the company start producing the same pack size they will not be allowed not more than Rs.16. They pointed out that this is unfavourable to the company.

6. The company representative further mentioned that NPPA had applied monopoly condition contained in para 6 of DPCO 2013 while para 6 applies only to scheduled formulation and not to new drug.

NPPA comments:

7. NPPA representative stated that DPCO 2013 provides only 2 formulas for price fixation i.e. average basis under para 4(1) and monopoly basis under para 6(1). Since only one manufacturer exists, price has been fixed by applying monopoly condition as per para 6(1) of DPCO 2013. This has been done uniformly applied in all other similar cases.

Examination:

7. One point raised by the company is that monopoly condition under para 6 should not have been applied to them as it applies only to scheduled formulations.

8. Other point raised by the company is that the same formulation with same strength manufactured by M/s Hema Laboratories and marketed by M/s J.B. Chemicals is being sold in the market at a MRP of Rs. 69.50 per 100 ml. J.B. Chemicals has launched another pack of 30 ml. with an MRP less than Rs.38. However, the company has been allowed a MRP less than Rs. 53 for 100 ml and it will be around Rs. 16 for 30 ml. The company has stated that this is unfavourable to the company.

9. In its 23rd Meeting of Authority under DPCO, 2013 held on 13.07.2015 NPPA has reversed its own decision of applying the provisions of para 6 in case of existence of only one manufacturer Reversing of its own decision by NPPA which, if applied to the instant case, the company will have no grievance. It is, therefore, recommended as under:-

Decision:

10. The Review Application of the company may be rejected.

Issued on this date, the 30th day of August, 2016.

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

To

1. M/s. Magnet Labs Ltd.,
236 Okhla Indl. Estate, Phase 3,
New Delhi-110020.

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. T.D., NIC for uploading the order on Department's Website.