

No. 31015/1/2015-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. Torrent Pharmaceuticals Ltd. against fixation/revision of ceiling prices of Paclitaxel (Nab Tortaxel) Injection vide NPPA notification S.O. No. 3147(E) dated 10/12/2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 29.12.2014
 2) NPPA notification under review S.O. No.3147(E) dated 10/12/2014
 3) Record Note of discussions held in the personal hearing held in the matter on 21.1.2015

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 3147(E) dated 10/12/2014 fixed/revised ceiling price of Paclitaxel (Nab Tortaxel) Injection under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/s Torrent Pharmaceuticals Pvt. Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 29.12.2014 under para 31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 3147(E) dated 10/12/2014 fixing Ceiling price of Paclitaxel (Nab Tortaxel) Injection under DPCO, 2013.

3. The grievance of the Petitioner raised in their review application dated 29.12.2014 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the Record Note of discussions held in the hearing on 21.1.2015. 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 Department's comments on the issue is recorded subsequently against each point:

4. Petitioner: The petitioner's representative mentioned that they intend to market Nab Tortaxel injection 100 mg which is being manufactured by M/s Panacea Biotech Ltd. Torrent is already marketing Paclitaxel injection (plain). As per provision contained in para 5 of DPCO, 2013 the new drug price should have been allowed after calculating average prices of same formulations available in the market. The company representative also mentioned that there is one more company viz. Zydus marketing the same formulation manufactured by M/s Panacea. The retail price of that is Rs.11640. The data of that company has not been taken into account by NPPA.

5. The petitioner's representative also mentioned that the price fixation should be as per the provisions of DPCO, 2013. The petitioner's representative further mentioned that if they are to market the product manufactured by Cipla or Biocon would NPPA allow the higher MRP than what is currently suggested since the MRP of these two companies are on the higher side. This kind of bench marking is not a precedence and not as per provision of DPCO 2013. In view of the above, the company representative requested to refix the price as per the provisions of DPCO 2013.

6. NPPA comments: The NPPA representative mentioned that M/s Panacea Biotech was also manufacturing the same combination at PTR of Rs.6857.14 as on December, 2013 after allowing 16% retail margin the retail price worked out to Rs.7954.28 per vial. Since the manufacturer of the formulation was already in the Market, the Authority decided that a higher price based on the principle of averaging would not be proper and thus the price at which the product is already available in the market of the same manufacturer was extended to M/s Torrent Pharmaceuticals also.

Government's comments and recommendation:

7. The petitioner's representative mentioned that Paclitaxel injection (plain) is a scheduled formulation. They had applied in Form I for fixation of price of new drug NAB Tortaxel injection which is being manufactured by M/s Panacea Biotech. NPPA has allowed Panacea Biotech PTR of Rs.6857.14 and after adding 16% retail margin the retail price worked out to Rs. 7954.28 per vial. The grievance of the company is that the prices should have been fixed as per provisions of DPCO 2013 and the calculation of retail price of a new drug is provided for under para 5(1). As per these provisions the retail price of new drug for existing manufacturer of a scheduled formulation shall be calculated as provided in sub para 1 of paragraph 4. Sub para 1 of para 4 provides for averaging the price to retailer of all brands and generic versions of the medicines having market share of more than or equivalent to 1% of the total market turn over. The action of NPPA in overlooking the provisions of para 5(1) of DPCO 2013 and deciding that a higher price based on the principle of averaging would not be proper is not as per the provisions of DPCO 2013. If NPPA feels that by applying the provisions of DPCO 2013 the prices fixed are unjustified or price aberrations exist in the market they should advise the Department for taking corrective measures for application across the board under the provisions of DPCO rather than taking decisions on stand alone cases which has no basis.

Recommendation

8. NPPA may be directed to fix the prices as per the provisions of para 5(1) of DPCO 2013.

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

“NPPA may be directed to fix the prices as per the provisions of para 5(1) of DPCO 2013.”

Issued on this 14th July, 2015.

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

To

1. M/s. Torrent Pharmaceuticals Ltd.,
Torrent House,
Off Ashram Road
Ahmedabad-380009
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.