

No.31015/14/2019-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

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A Wing, Shastri Bhawan,  
New Delhi-110 001.

Order

1. This is an order disposing of a review application dated 13.09.2019, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Emcure Pharmaceuticals Limited (hereinafter called the applicant) against notification S.O. No.3032(E), dated 23.08.2019 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail prices of Emtricitabine + Tenofovir tablet containing Emtricitabine IP 200mg, Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg and Dolutegravir + Emtricitabine + Tenofovir Alafenamide tablet containing Dolutegravir Sodium eq to Dolutegravir 50mg., Emtricitabine IP 200mg., Tenofovir Alafenamide Fumarate eq. to Tenofovir Alafenamide 25mg.

2. The main contentions of the applicant are as given below :

(i) The company submitted Form I applications for the Retail Price approval of Emtricitabine 200 mg plus Tenofovir Alafenamide 25 mg Tablet (TAF-E) to NPPA on 3rd July 2019 and Dolutegravir 50 mg plus Emtricitabine 200 mg plus Tenofovir Alafenamide 25 mg Tablet (TAF-ED) on 7<sup>th</sup> May 2019. NPPA has notified the retail price as 51.34/Tab and 130.60/tab, respectively vide S.O. 3032(E) dtd. 23.08.2019.

(ii) Earlier, the NPPA fixed the retail price of Emtricitabine 200 mg plus Tenofovir Alafenamide 25 mg for M/s Cipla Ltd. and M/s Mylan Pharmaceuticals Pvt. Ltd. vide S.O. 1489(E) dtd. 29th March 2019 at 55.33/tablet based on the recommendation of Multidisciplinary Committee of Experts in its 8th Meeting held on 18.3.2019.

(iii) For the computation of Retail Price for TAF-E, NPPA used the PTR for the month of April 2019 of M/s Hetero Healthcare Ltd as per PharmaTrac data and the draft working sheet was uploaded on NPPA website on 31.07.2019. However, the company came to know from the minutes of meeting of 69<sup>th</sup> Authority meeting of the NPPA that M/s Hetero Healthcare Ltd. *had not obtained prior price approval, before launch of the subject formulation and directed for issue of notice to M/s Hetero Healthcare Ltd for non-compliance to the orders of DPCO. Therefore, their case cannot be compared to the above one as company has followed the 'Rule of Law' as per the existing provisions of DPCO.*

(iv) The company further stated that the NPPA has exercised the practice to not to consider the PTR of WPA case in working out the retail price of a formulation in the past also, e.g. Retail Price of Paracetamol 325 mg plus Hyoscine Butylbromide 10 mg tablets (Buscogast Plus Tablets) and the *data of M/s German Remedies India Pvt. Ltd.*

and ACME Pvt. Ltd. were not considered **as they were marketing their packs without price approval**. The company cited the case of DoP's review order, dated 22.07.2016 in case of review filed by M/s Boehringer Ingelheim India Pvt. Ltd. in this regard.

(v) The company further stated that the NPPA has considered the PTR of April 2019 instead of November 2018 for Retail Price fixation considering the amendment in para 9(7) vide DoP's S.O. 39(E) issued by the Department dtd. 3rd January 2019. However, NPPA has ignored the fact that the same methodology can only be considered for fixing the ceiling price and not the retail price. The retail price should have been fixed by extending the Retail price of Emtricitabine 200 mg plus Tenofovir Alafenamide 25 mg fixed for M/s Cipla Ltd. and M/s Mylan Pharmaceuticals Pvt. Ltd. vide S.O. 1489(E) dtd. 29th March 2019 as PharmaTrac does not show any other brand other than that of M/s Hetero Healthcare Ltd.

(v) The NPPA has not extended the benefit of 4.2662% increase based on the annual increase in Wholesale Price Index (WPI). In this regard, the company cited the decision vide DoP's review order (*No.31015/10/2019-Pricing*) on a review application filed by M/s Cipla Ltd. challenging the S.O. 1489(E) dtd. 29th March 2019, wherein the Department has directed NPPA to extend the benefit of 4.2662% increase based on the annual increase in Wholesale Price Index (as given in the ceiling price of scheduled medicine Tenofovir 300mg vide SO 1485(E), dated 29.03.2019 and revise the Retail Prices of subject formulation.

The company appealed DoP to advise/direct NPPA to revise the retail prices based on the provisions of DPCO, 2013 to ensure just & equitable retail prices to company's both formulations as stated above.

### 3. NPPA's comments:

3.1 The NPPA placed the draft version of price calculation sheet on its website on 31.07.2019 and the minutes of the 12<sup>th</sup> Meeting of Multi Disciplinary Committee of Experts in order to take into account the observations from affected pharmaceutical companies before finalizing the retail price of subject formulations.

3.2 M/s Emcure Pharmaceuticals Limited vide its letter no EPL/NPPA/141 dated 01.08.2019 stated that they have accepted the retail price proposed in the draft working sheet against their above said formulations and requested the NPPA to include their form I application in the next Meeting of the Authority so that the price can be fixed at the earliest. Since, the company has already accepted the retail price; the issue raised by the company in its review application has no merit.

### 4. Examination:

4.1 The Department of Pharmaceuticals vide OM No.31015/44/2016-PI.I, dated 11<sup>th</sup> July, 2016 had directed the NPPA to place a draft version of the price calculation sheets for the proposed price notifications, indicating the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, wherever application, on the website of the NPPA for 10 clear working days to invite comments from the affected pharmaceutical firms. Only after taking into account the comments of any

additional data thus received within the given time period, the NPPA shall finalize the ceiling and the retail prices. The above decision was taken to maintain transparency and avoid review application by the pharmaceutical firms after issue of price notification.

4.2 Accordingly, the NPPA placed the draft version of price calculation sheets on its website on 31.07.2019. Thereafter, the company, viz. M/s Emcure Pharmaceuticals Limited, vide its letter no EPL/NPPA/141 dated 01.08.2019 accepted the retail prices proposed in the draft working sheets against its above said formulations and requested the NPPA to include their form I application in the next Meeting of the Authority so that the prices can be fixed at the earliest. Thereafter, the price notification was issued by the NPPA on 23.08.2019.

4.3 Since the applicant had conveyed its acceptance to the proposed retail prices in the draft calculation sheets, the retail prices fixed by the NPPA cannot be disputed now. Therefore, the review application is not tenable and deserves to be rejected.

5. Decision:

The draft version of calculation sheets for the proposed retail price fixation of “Emtricitabine IP 200mg plus Tenofovir Alafenamide 25mg tablet” and “Dolutegravir 50mg plus Emtricitabine 200mg plus Tenofovir Alafenamide 25mg tablet” were placed by the NPPA on its website on 31.07.2019, which was accepted by the applicant on 01.08.2019. The retail prices fixed accordingly, cannot be disputed now. Therefore, the review application is not tenable and stands rejected.

Issued on this, the 10<sup>th</sup> day of January, 2020.

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

Copy to :-

1. M/s Emcure Pharmaceuticals Limited, Emcure House, T-185, M.I.D.C., Bhosari, Pune-411 026.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001.
3. PS to Hon'ble Minister(C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary(Pharma), Shastri Bhawan, New Delhi for information.
6. Joint Secretary(Pharma), Shastri Bhawan, New Delhi for information.
7. T.D., NIC for uploading the order on Department's Website.