

No.31015/09/2019-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

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

Order

1. This is an order disposing of a review application dated 26.04.2019, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Mylan Pharmaceuticals Private Limited (hereinafter called the applicant) against notification S.O. No.1489(E), dated 29.03.2019 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail prices of Tenofovir Alafenamide Fumarate (TAF) 25mg tablet and Tenofovir Alafenamide Fumarate 25mg+Emtricitabine 200mg tablet.

2. The main contentions of the applicant are that –

(i) The Multidisciplinary Committee of Experts has failed to take into account critical facts and data in order to arrive at a holistic assessment of the price to be determined for Tenofovir Alafenamide Fumarate (TAF).

(ii) The company stated that TAF falls under Explanation 5 in Schedule I of DPCO, 2013 which stipulates that in cases where an active moiety is available as different isomers or analogues or derivatives, they are considered separate entities, and inclusion of one does not imply inclusion of all isomers or analogues or derivatives. Thus inclusion of Tenofovir in the DPCO schedule does not automatically imply inclusion of all isomers, analogues and derivatives of the same.

(iii) The company further stated that TAF falls under Explanation 2 in Schedule 1 of DPCO, 2013, which states that (i) innovation in medicine must be encouraged; and (ii) the formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/controlled release etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing etc.

(iv) The company pleaded that for the purpose of determination of a price of new drug, mere therapeutic equivalence or, similar clinical efficacy as an existing formulation cannot be the sole basis and due regard has to be given to incremental innovations that have been made in a formulation, resulting in a novel formulation with improved drug delivery and better safety profile.

2.2 The company prayed to re-consider the price fixed for TAF and TAF plus Emtricitabine combination considering TAF as a novel formulation with an incremental innovation in the formulation of Tenofovir, resulting in improved drug delivery and better safety profile.

3. NPPA's comments:

The NPPA's Authority fixed the retail price of Tenofovir Alfenamide Fumarate (TAF) 25mg and Tenofovir Alfenamide Fumarate (TAF) 25mg+ Emtricitabine 200mg tablet based on the recommendation of Multidisciplinary Committee of Experts in its 8<sup>th</sup> Meeting held on 18.3.2019. While making the recommendation, the Multidisciplinary Committee of Expert has gone through all the technical matters submitted by the company.

4. Examination:

4.1 The issues relating to incremental innovation or novel drug delivery systems, sustained release/controlled release etc. in the formulations, therapeutic rationale and other related issues, are referred by NPPA to the Multidisciplinary Committee of Experts for examination and its recommendations. The Expert Committee is well represented by very senior Professors and Doctors and other experts in the field, who are capable enough to understand the therapeutic rationale of any drug/formulation.

4.2 The matter of retail price fixation of the Tenofovir Alfenamide Fumarate (TAF) 25mg was discussed thrice (in its 6<sup>th</sup>, 7<sup>th</sup> and 8<sup>th</sup> meetings) by the Multidisciplinary Committee of Experts. The recommendation of the Committee was made on a scientific basis by comparing therapeutic value of one pharmaceutical drug to another as per the provisions of the DPCO, 2013 and the Committee of Experts has rightly recommended the price of Tenofovir Alafenamide Fumarate (TAF) 25mg tablet and TAF plus Emtricitabine 200mg tablet, which has been subsequently fixed by NPPA.

4.3 In view of the above, the rationale put forth by the company in its review application for reconsideration of the matter by NPPA cannot be accepted and needs to be rejected.

5. Decision:

The review application filed by the applicant is devoid of any merit and hence stands rejected.

Issued on this, the 17<sup>th</sup> day of July, 2019.

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

Copy to :-

1. M/s Mylan Pharmaceuticals Private Limited, No.32/1&2, 34/1 to 4, 7<sup>th</sup> to 12<sup>th</sup> Floor, Prestige Platina, Block 3, Kadubesanahalli Village, Varthur Hobli, Outer Ring Road, Bangalore East Taluk, Bengaluru-560 087.
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.