

No.31015/10/2019-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 26.04.2019, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Cipla 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 Emtricitabine+ Tenofovir Alafenamide tablet (brand Tafmune – EM) containing Emtricitabine IP 200mg, Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg; Tenofovir Alafenamide tablet containing Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg and Emtricitabine+Tenofovir Alafenamide tablet containing Emtricitabine IP 200mg, Tenofovir Alafenamide Fumarate Hemifumarate eq. to Tenofovir Alafenamide 10mg tablet.

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

(i) The formulation Tenofovir Alafenamide Fumarate (TAF) 25mg tablet cannot be claimed to be therapeutically equivalent to Tenofovir 300mg tablet and thus the ceiling price of Tenofovir 300mg tablet cannot be made applicable to the subject formulation.

(ii) The Experts Committee is required to make recommendations of the retail price as per the principles of 'Pharmacoeconomics' in terms of Para 15 of the DPCO.

(iii) By virtue of SO 1485(E), dated 29th March, 2019, the ceiling price of Tenofovir 300mg tablet has been increased by 4.2662% on the basis of the annual increase in WPI, and has been notified at Rs. 46.18. The benefit of this increase in the ceiling price of Tenofovir 25mg by approximately 4% has not been given.

(iv) With respect to the formulation of Emtricitabine IP 200mg tablet and Tenofovir Alafenamide Tablet 10mg, the Expert committee has relied on the formula prescribed by the Pronab Sen Committee, report which was submitted on September 30, 2005 and as such may not be an accurate indicator of the present times.

2.2 The company prayed to re-calculate and re-fix the retail prices of the subject formulations after calling for information from all stakeholders.

3. NPPA's comments:

The NPPA's Authority fixed the retail price of Tenofovir Alafenamide Fumarate 25mg and Tenofovir Alafenamide Fumarate 25mg+ Emtricitabine 200mg tablet based on the recommendation of Multidisciplinary Committee of Experts in its 8th Meeting

held on 18.3.2019. While making the recommendation, the Multidisciplinary Committee of Experts has gone through all the technical matters submitted by the company.

4. Examination:

4.1 The issues relating to incremental innovation in the formulations, therapeutic rationale and other related issues, were deliberated in-depth in the 6th, 7th and 8th meetings of Multidisciplinary Committee of Experts. The representations of Pharma companies manufacturing TAF were also considered by the Expert Committee. 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. The recommendation by the Multidisciplinary Committee of Experts was made on a scientific basis by comparing therapeutic value of one pharmaceutical drug to that of another as per the provisions of the DPCO. Therefore, based on the recommendation of the Multidisciplinary Committee of Experts, the NPPA has rightly extended the price of Tenofovir 300mg tablet to TAF 25mg tablet.

4.2 The Multidisciplinary Committee of Experts recommended the retail price of Emtricitabine IP 200mg tablet and Tenofovir Alafenamide Tablet 10mg. based on the principles of “pharmacoeconomics” by applying Pronab Sen Committee formula. The Pronab Sen Committee formula is as given below :-

$$P(s) = P^*.[1 + a.\{(s - s^*)/s^*\}]$$

Where: P(s) = price ceiling for strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a = constant such that 0 < a < 1

The constant ‘a’ in the above formula recognizes that the cost of production of a tablet or injection decreases as the strength is increased. However it is also recognized that the other ‘costs’, such as promotional expenses and profit margins, which constitute a substantial fraction of the price of a formulation, do not exhibit the same behaviour. Therefore, great care needs to be taken to ensure that ‘a’ is not chosen in a manner that incentivises companies to produce non-standard strengths in order to maximise profits. Preliminary exercises carried out by the Task Force indicate that the appropriate value of ‘a’ is 0.8 for tablets/capsules and 0.7 for injectibles.

The applicant failed to give any basis of its contention that this formula, given in 2005, may not be an accurate indicator of the present times. In the instant case, as the formulation is in tablet form, value of 0.8 is applied, and its application in fixing the retail price of this new drug is in order.

4.3 The NPPA should have extended the benefit of 4.2662% increase, as given in the ceiling price of scheduled medicine Tenofovir 300mg tablet vide SO 1485(E), dated 29.03.2010, based on annual increase in Wholesale Price Index (WPI), while fixing the retail price of formulation Tenofovir Alafenamide Fumarate 25mg. As the S.O. 1489(E), fixing the retail prices of subject formulations and S.O. 1485(E),

revising the ceiling prices of all scheduled formulations giving WPI impact were issued on same date, i.e. 29.03.2019, therefore, the grievance of the applicant is genuine.

5. Decision:

The NPPA has rightly extended the ceiling price of Tenofovir 300mg tablet to Tenofovir Alafenamide Fumarate 25mg tablet on the recommendation of Multidisciplinary Committee of Experts. There is no valid ground to interfere with the decision of the NPPA on this particular issue. Hence, the plea of applicant on this issue is rejected.

However, the NPPA is directed 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 formulations containing Emtricitabine IP 200mg+Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg; Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg and Emtricitabine IP 200mg+Tenofovir Alafenamide Fumarate Hemifumarate eq. to Tenofovir Alafenamide 10mg tablets of SO 1489(E), dated 29.03.2019 accordingly.

Issued on this, the 30th day of August, 2019.

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

Copy to :-

1. M/s Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400 013.
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.