No. 31015/5/2016-PI.I GOVERNMENT OF INDIA MINISTRY OF CHEMICALS & FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

.

B Wing, Janpath Bhavan, New Delhi 110 001

- Subject: The review application of M/s Emcure Pharmaceuticals Ltd dated 19/04/2016 under para 31 of DPCO against NPPA order No. S.O. 1253(E) dated 29/03/2016 for price fixation of A-Bec Tablet (Abacavir 600 mg + Lamivudine 300 mg).
- Ref: 1) Review application dated 19.04.2016
 2) NPPA notification under review S.O. No.1253(E) dated 29.3.2016
 3) Record Note of discussions held in the personal hearings held in the matter on 11.5.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Emcure Pharmaceuticals Ltd. (hereinafter called the petitioner) against notification S.O. No.1253(E) dated 29.03.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of A-Bec Tablet (Abacavir 600 mg + Lamivudine 300 mg).

2. The petitioner has contended as under:

Company's Submission:

- The company submitted that by the Notification, the revised pricing for their formulation A-Bec L while calculating ceiling price, PTR considered for their brand is Rs.129.10 for pack of 30 tablets i.e. Rs. 4.30 per tablet. This PTR is not based on realistic data and need to be revised.
 M.R.P. of their product is Rs.2950 per pack of 30 tablets which is followed by them from September, 2009.
- (ii) They stated that they have explained these facts vide their letter no. EPL/NPPA/024 dated 06/04/2016 addressed to National Pharmaceutical Pricing Authority with supporting documents such as price list filed on 30th September, 2009, market samples, PTR of their product Rs.2247.62 and actual sales for the period September, 2014 to August 2015, Rs. 0.81 crores.
- (iii) They stated that they have already implemented the ceiling price declared on 29th March, 2016. Further they requested this Department to kindly go through their application and the rationale which was used to arrive at the revised pricing for Abacavir 600 mg. + Lamivudine 300 mg tablet.

Comments of NPPA:

NPPA representative mentioned that the representation submitted by company has been examined by the NPPA and the matter with relevant data will be placed before the next meeting of the Authority.

3. In the personal hearing, the company representative informed that they have submitted the correct data for fixation of selling price of A-Bec L Tablet (Abacavir 600 mg + Lamivudine 300 mg) and the data is understood to have been ratified by Pharmatrac also. The company representative requested that the refixation of the product may kindly be got done at the earliest possible. On this, the NPPA representative stated that the representation submitted by the company has been examined by the NPPA and the matter with relevant data will be placed before the next meeting of the Authority and accordingly the matter will be decided.

4. **Decision of the Government:**

NPPA has already revised the ceiling price of A-Bec Tablet (Abacavir 600 mg+Lamivudine 300 mg) to Rs.84.55 vide their SO 1817(E), dated 18.5.2016

In view of the above, the present review petition stands disposed off.

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

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

То

- M/s. Emcure Pharmaceuticals Lt., Emcure House, T-184, M.I.D.C., Bhosari, Pune-411 026.
- 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