

No. 31015/12/2014-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan,
New Delhi 110 001

O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s Abbott Healthcare Private Limited against price fixation of "Famotidine Tablet 20 mg" vide NPPA order No. S.O. 1016(E) dated 02.04.2014 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 15.04.2014
2) NPPA notification under review S.O. No.1016(E) dated 2.4.2014
3) Record Note of discussions held in the personal hearings held in the matter on 28.6.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s **Abbott Healthcare Private Limited** (hereinafter called the petitioner) against notification S.O. No.1016(E) dated 02.04.2014 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of "**Famotidine Tablet 20 mg**".

2. The issues involved in the review application have been examined based on record note of discussions of the personal hearing, other documents on record and the Government decided as under :

"NPPA is directed to revalidate the data of the petitioner as empowered under para 9 of DPCO, 2013. Whether Gelatin coated tablets are technologically different and deserve a different ceiling price the matter may be referred to Standing Technical Committee for advice. The petitioner in the meantime is directed to maintain the ceiling price already notified by NPPA."

Department had issued the Order to this effect on 5th August, 2014.

3. Thereafter, a presentation was given by the company in the Standing Technical Committee Meeting No.15, held on 16.11.2015, highlighting certain advantages of gelatine coated famotidine tablet over the plain tablet. The company mentioned that the gelatine coated tablets are tehnologically advanced product and hence, should be priced separately than the plain tablets, but there is no therapeutic benefit as informed by the company to the members of the Standing Technical Committee during their presentation.

4. The reviewing authority noted that as there is no therapeutic value for the patients and also there is no provision in the DPCO to consider gelatine coating differently. Hence, the technical issues raised by the Company during the personal hearing has no merit and review petition of the company is rejected.

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

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

To

1. **M/s. Abbott Healthcare Private Limited**
D Mart Bldg.,
Goregaon Mulund Link Road,
Mulund West,
MUMBAI-400 080.
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**