

No. 31015/26/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: Review application of M/s Baxter (India) Pvt. Ltd. against price fixation of Coagulation Factor VIII vide NPPA order No. S.O. 1405(E), dated 12.4.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 11.05.2016
2) NPPA notification under review S.O. No.1405(E), dated 12.4.2016
3) Record Note of discussions held in the personal hearing held in the matter on 21.6.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Baxter (India) Pvt. Ltd. (hereinafter called the petitioner) against notification S.O. No.1405(E), dated 12.4.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Coagulation Factor VIII.

2. The petitioner has contended as under:

- i. Their key product Hemofil M (Coagulation Factor VIII injections) Plasma derived have not been taken on record by the Honorable NPPA at the time of Price fixation.
- ii. Currently, the ceiling price as per the mentioned order has been set at Rs. 3,323/- for 250IU dosage, taking into consideration Price to Retailer (PTR) of Intas Pharmaceuticals and Reliance Life Sciences as per working sheet dated 13th April, 2016 relating to Prices as notified on 12th April, 2016.
- iii. Baxter India holds >80 % of the market for Plasma derived Coagulation Factor VIII. Below is a detailed list of their products along with prices before the notification of Rs. 3,323/- ceiling. As mentioned above, prices for these products have not been considered during determining price ceiling for Coagulation Factor VIII, as notified on 12th April, 2016.

Composition as per NLEM	Pack Description	Brand	Company	Strength	Pack	Unit	PTR	MAT
Factor VIII Including	Hemofil M Low 250 IU	Hemofil M	Baxter	250 IU	1	1	3299	

They requested this Department to consider the price information for and Hemofil M as supplied by and notify the updated ceiling price for Coagulation Factor VIII.

Comments of NPPA:

- (i) NPPA has fixed the ceiling price Rs. 3323.60 per pack for Coagulation Factor VIII vide S.O 1405(E) dated 12/04/2016 under para 4, 10, 11, 14 & 16 of DPCO, 2013.
- (ii) Company is directed to approach NPPA in line with OM F. No. 19(714)/2016/Div.II/DP/NPPA dated 20/05/2016.
- (iii) Requisite information/documents by the company will be examined and suitable action may be taken by the Authority in this regard.

3. The contentions of petitioner and the NPPA were heard on 21st June, 2016. During the hearing, the petitioner company did not submit any more submission. NPPA representative requested the hearing authority to direct the company to submit the documents/information as per OM F.No.19(714)/2016/Div.II/DP/NPPA, dt.20th May, 2016.

6. **Government Decision:**

NPPA is directed to re-fix the ceiling price of “Coagulation Factor VIII” after taking into consideration all data, furnished by the petitioner company and available from other sources, on merit within a period of one month from the date of issue of the Order of Reviewing Authority.

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

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

To

1. **M/s.Baxter (India) Pvt. Ltd.,
2nd Floor, Tower C, Building No.8,
DLF Cyber City, DLF Phase-II,
Gurgaon-122 002.**
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**