

No.31015/7/2013-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s Sun Pharmaceutical Industries Limited under para 22 of DPCO 1995 against price fixation of “Histac EVT 2’s Al Strip and Fucibet Cream 15 gm Al Tube” vide NPPA order No. S.O. 579(E) dated 24.02.2016 based on review order No.31015/7/2013-PI.I, dated 7.10.2015.

Ref: 1) Review application dated 08.03.2016
2) NPPA notification under review S.O. No.579(E) dated 24.02.2016
3) Record Note of discussions held in the personal hearing held in the matter on 19.09.2016.

1. This is a petition under paragraph 22 of the Drugs (Prices Control) Order, 1995 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Limited (hereinafter called the petitioner) against notification S.O. No.579(E) dated 24.02.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Histac EVT 2’s Al Strip and Fucibet Cream 15 gm Al Tube based on review order No.31015/7/2013-PI.I, dated 7.10.2015.

2. The petitioner has contended as under:

I. They referred to Department of Pharmaceuticals review order no. 31015/7/2013-PI.I dated 07.10.2015 and subsequently NPPA notification S.O.No.579(E) dated 24.02.2016 revising the price of Histac EVT 2’s Al Strip pack from Rs.2.96 to Rs.3.68 and Fucibet Cream 15 gm Al Tube pack from Rs.30.52 to Rs.46.22 excluding excise duty and local taxes under DPCO, 1995 based on the review order of the Ministry and being aggrieved by the said inadequate revision in price seek review of the same under Paragraph 22 of DPCO, 1995 on the following grounds:-

- (i) They had submitted their application in Form III prescribed under DPCO, 1995 which was kept pending at NPPA despite all the details provided by us on grounds which were not justified and disclosed to us and the closure of the same was communicated to us on the ground of announcement of NPPP-2012 which had not even become operative.
 - (ii) Even after Court intervention and Review Order of the Ministry dated 7th Oct, 2015, the prices have not been properly fixed.
 - (iii) The production of Histac EVT Tablets involves a special process and requires dedicated facilities and this aspect have been totally ignored.
 - (iv) They sought a price of
- a) **Rs.5.16 for Histac EVT** Al strip of 2 tablets which being Hygroscopic require such packaging material and raw material cost based on actuals.

- b) **Rs.69.08 for Fucibet Cream** which is sterile and packed in lacquered Al Tube based on actual cost as submitted by us and the relevant norms for conversion cost and packing charges.

However, it seems that unjustifiable reductions have been made in the costs without disclosing or assigning any reasons. Necessary disclosures should have been made to them.

- (v) Norms of conversion cost, packing charges and packing materials have not been revised based on established procedure of costing after the year 2006 and as such norms for conversion cost are not correct.
- (vi) Histac EVT tablets and Fucibet 15 gm cream have become nonscheduled formulation under DPCO, 2013 and although inadequate price have been fixed but its base year is April 2012 and Oct 2012 respectively when they submitted their price application.
- (vii) They were entitled to 10% annual increase in price under the provisions of paragraph 10 read with Paragraph 20 of DPCO, 2013. As they have already taken the 10% annual increase in last three years, their existing MRP is almost near to the prices fixed by NPPA. Therefore considering this, they should be allowed to take an annual increase of 10% for last 3 years, over the prices fixed by NPPA, as mentioned below:

Product	Price fixed by NPPA on 24.02.2016	Year 2013	Year 2014	Year 2015	Expected Current Price
Histac EVT	3.68	4.05	4.45	4.90	4.90
Fucibet 15 gm Aluminium Tube	46.22	46.22	50.84	55.93	61.52

(Price in Rs.)

- II. Further, this expected current price becomes due for further revision on completion of one year or revision of base price based on their review application. The above aspects may please be taken on record.

Comments of NPPA:

- (i) The retail price of Rs.3.68 per 2 tablet for **Histac EVT 2's AL strip** and Rs.46.22 for **Fucibet Cream 15mg Al tube** was fixed by NPPA vide S.O. 579(E) dated 24.02.2016 as per para 8 of DPCO, 1995.
- (ii) **Fucibet Cream 15mg Al tube** remains a non-scheduled formulation under DPCO 2013. However, the company will have to maintain prices fixed by NPPA for a period of 12 months, after which only company can claim 10% hike. Company is also requested to follow OM no 19(119)/2014/Div.II/NPPA dated 06.4.2016.

- (iii) **Histac EVT 2's AL strip** in non-scheduled formulation under NLEM 2011 of DPCO 2013 and company may revise the retail price based on para 10 & 20 of DPCO 2013. NPPA has fixed the ceiling price Rs. 0.69/tablet for Ranitidine 150mg tablet vide S.O. 1253(E) dated 01.4.2016, therefore company will have to follow the ceiling price fixed in this regard.
- (iv) As per information available with M&E division (through IPDMS report), company has not submitted Form – V in support of the compliance of retail / ceiling price for **Fucibet Cream & Histac EVT 2's AL strip** fixed vide S.O. 579(E) dated 25.02.2016 & S.O. 1253(E) dated 29.3.2016. DOP is also requested to verify the same from the company by insisting on verified copies of the control sample of price revision and relevant invoices in support.

3. During the personal hearing, the company representative submitted the hard copy of Form V to the compliance of price notification. The company representative submitted brief of both the cases in chronological order.

Company representative further mentioned that from the data available with them which was used by NPPA while fixing the revised price, NPPA has considered Histac EVT as an Excise Paid product and for Fucibet cream, norms for unlaquered tube were applied. NPPA could have very well sought the clarification from the company before deciding of its own as above. Company representative has humbly requested to consider 10% annual increase for three years as submitted in the review application as the retail price fixed by NPPA is with the cost data 'Conversion Cost Packing Charges' (CCPC) norms for the year 2012.

NPPA representative submitted that the price has been fixed based on the data submitted by the company. Further, if there is any other data/information, which is required to be furnished by the company, they should have submitted the same along with the original Form-III. In DPCO 1995, there was no provision for annual increase while fixation of price.

4. **Examination:**

The case has already been examined in detail in the last review of the application filed by the company. In the case of Histac EVT, the bulk drug Ranitidine 150 mg is a scheduled formulation as per NLEM 2015. Therefore, the price fixed by the NPPA vide S.O. 1253(E) dated 01.4.2016 is applicable for Histac EVT and is valid until some ambiguity is pointed out in the method of calculation included in the working sheet. As such, the grievance of the company has got no merit and deserves to be rejected.

As regards, Fucibet cream, as it contains Fusidic Acid as API and it was not included either in NLEM 2011 or NLEM 2015, the provisions applicable for non-scheduled formulations as per DPCO needs to be applied. Therefore the request of the applicant in this case deserves consideration.

5. **Government Decision:**

“The grievance of the petitioner company in respect of Histac EVT 2’s AI strip has no merit and deserves to be rejected.

However, in case of Fucibet cream 15 mg AI tube, as it was not included either in NLEM 2011 or NLEM 2015, the provisions applicable for non-scheduled formulations as per DPCO needs to be applied. Therefore, NPPA is directed to fix the price of Fucibet cream 15 mg AI tube as per provisions applicable for non-scheduled formulations in DPCO, 2013, within 30 days from the date of issue of this order.”

Issued on this date of 21st day of June, 2017.

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

To

1. M/s. Sun Pharmaceutical Industries Limited,
8-C, 8th Floor, Hansalya Building,
15-Barakhamba Road, Connaught Place,
New Delhi-110001.
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