

No. 31015/73/2016-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 Sun Pharmaceutical Industries Limited against price fixation of “Volitra AQ Injection (Diclofenac Sodium Injection 75 mg/ml)” vide NPPA order No. S.O. 2195(E) [corrected SO No.2194(E)] dated 23.06.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 21.07.2016
2) NPPA notification under review S.O. No.2195(E) [corrected SO No.2194(E)] dated 23.06.2016
3) Record Note of discussions held in the personal hearing held in the matter on 06.09.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Limited (hereinafter called the petitioner) against notification S.O. No.2195(E)[corrected SO No.2194(E)] dated 23.06.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Volitra AQ Injection (Diclofenac Sodium Injection 75 mg/ml).

2. The petitioner has contended as under:

- I. They referred to their Form-I application dated 06.05.2016 applied for price fixation of Diclofenac Sodium Injection 75 mg/ml under DPCO 2013. Retail price of this formulation was notified by NPPA via S.O. 2195(E) **{Corrected S.O. No. 2194(E)}** dated 23.06.2016 as Rs. 14.3 per ml. They had requested the office of National Pharmaceutical Pricing Authority (NPPA) to provide them the working sheet/ calculation copy of the retail price of Rs. 14.3/ml to understand the price calculation, as there was difference in their claimed price, based on market data of 6 months prior to the date of Form-I filing as per para 9(4) of DPCO 2013, and what they have been notified. They are aggrieved by this retail price notification of Rs. 14.3 per ml and therefore seek a review of the same under paragraph 31 of DPCO 2013 on the following grounds:
 - (i) They had provided the market data of Diclofenac Sodium Injection 75 mg/ml of November 2015 & December 2015, i.e. data of 6 months prior to the date of filing of Form-I, as per para 9(4) of DPCO 2013.
 - (ii) They had requested the office of NPPA for providing them the working sheet/ calculation copy of retail price of Rs. 14.3 per ml through their letter dated 27.06.2016, and 18.07.2016, however they have not received any details so far.

- II. In view of the above, they requested this Department to kindly issue necessary directives to NPPA to provide them the calculation copy of retail price of Diclofenac Sodium Injection of Rs. 14.3 per ml.

Comments of NPPA:

- (i) NPPA has fixed the retail price of Rs. 14.30/ml based on the Form-I application submitted by M/s Nitin Lifesciences (Ltd.) (manufacturer) and M/s Galpha lab Ltd. (marketing company) for the same composition vide S.O. 1562(E) dated 27/04/2016, as per the Authority decision taken in 14th meeting of Authority held on 23/04/2014 (copy enclosed) that the price shall be valid for one year.
- (ii) As per information available with M&E division (through IPDMS report), company has not submitted Form-V in respect of their formulation whose retail price was notified vide S.O. 2195(E) dated 23.6.2016. DOP is also requested to verify the same from the company before hearing.

3. During the personal hearing, the company representative submitted that they have applied for price approval in Form-I dated 06.05.2016 to NPPA for Diclofenac Sodium Injection 75 mg/ml along with all the pre-requisite documents. Being existing manufacturer of Diclofenac Sodium Injection 25mg/ml, Diclofenac Sodium Injection 75 mg/ml Injection is a new drug as per para 2(u) of DPCO 2013.

NPPA notified the Retail Price of 14.30 /ml via notification S.O. 2195(E) dated 23.06.2016. The company observed that the retail price of Rs. 14.30 /ml was not as per market data of November 2015, which is 6 months prior of date of application, as per para 9(4) of DPCO 2013. The company submitted representation to the office of NPPA for providing the calculation sheet in arriving at the retail price of Rs. 14.30/ml to understand the calculation. In reply, NPPA sent a letter to the company stating that the price notified is Rs. 14.3/ml, and they have to comply with this price.

The company raised their grievance to Department of Pharmaceuticals via its review application dated 21.07.2016 stating that the calculation data of Retail Price not provided by NPPA and Retail Price not fixed as per paragraph 9(4) of DPCO 2013.

The company has launched the product in the market based on the Retail Price fixed by NPPA at MRP Rs. 15.00 (Retail Price 14.30 +VAT 5%) under compliance as per paragraph 31 of DPCO 2013 in filing review application and seeking suitable intervention.

The company representatives have asked for the calculation sheet of the retail price Rs.14.30 per ml. In support of that, they have also submitted the scanned copy of the product pack in confirmation with the retail price of Rs.14.30 per ml. Company has requested to fix the retail price as per para 9(4) of DPCO, 2013 considering current market scenario.

NPPA representative submitted that the retail price of Volitra AQ Injection (Diclofenac Sodium 75 mg/ml) has been fixed by the Authority as per the existing practice.

4. **Examination:**

As per provision of para 5(1) read with para 9(4) of DPCO 2013 NPPA is required to consider the PTR of available drugs in the market, take simple average of all those who have more than 1% market share and consider the new drug price as per the simple average formula contained in para 4(1) of DPCO 2013. NPPA has fixed the retail price of Rs. 14.30/ml based on the Form-I application submitted by M/s Nitin Lifesciences (Ltd.) (manufacturer) and M/s Galpha lab Ltd. (marketing company) for the same composition vide S.O. 1562(E) dated 27/04/2016, based on the decision taken in 14th meeting of Authority held on 23/04/2014 that the price for formulations having same composition and strength shall be valid for one year. This decision is not in accordance with the provisions of DPCO, 2013.

5. **Government Decision:**

Based on the above, the Government has decided as under:

“Review application of the company is accepted and NPPA is directed to re-fix the price as per the provisions of DPCO 2013 within one month of this Order, rather than deciding the prices on its own derived principles which are beyond the provisions of DPCO 2013. The calculation sheets should also be put up in the public domain.”

Issued on this date of 10th day of January, 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-110 001.
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