

**No. 31015/16/2018-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

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**A- Wing, Shastri Bhawan,  
New Delhi 110 001**

**Order**

1. This is an order on an application dated 14.02.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Sun Pharma Laboratories Limited. (hereinafter called the applicant) against notification S.O. No. 269(E), dated 16.01.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Amphotericin B (Liposomal) Injection 50mg.

2. The applicant has contended as under:-

2.1 NPPA while fixing the price of Formulation Amphotericin B (Liposomal) 50 mg injection, has

- (a) Considered the incorrect PTR of its product Lambin Injection 50 mg @ Rs. 3000/- per pack instead of the actual PTR in August 2015 i.e. Rs. 3610.90/- per pack.
- (b) Considered the prices of few formulations having MAT value less than 1% market share.

2.2 In response to Point (a) above, the NPPA confirmed that they have verified the PTR from Pharmatrac, in turn Pharmatrac has confirmed to them that the PTR of the formulation in question may be Rs. 3659/- per pack.

2.3 Company had already submitted the necessary documents, details and product pack of Lambin Injection 50 mg to NPPA office via their letters dated 26.12.2017, 29.12.2017, and 02.01.2018.

2.4 The Hon'ble reviewing authority was pleased to order that.

"NPPA is hereby directed to consider the actual PTR of formulation LAMBIN LYOPHILISED 50 MG Injection 1, and after verification, re-fix/revise the ceiling price of Amphotericin B (Liposomal) Injection 50 mg, on merit.

NPPA is further directed to re-fix and re-notify the ceiling price of formulation Amphotericin B (Liposomal) Injection 50 mg by considering the PTR of these formulations having MAT value of more than 1% market share, as per para 4 of DPCO 2013, as DPCO does not allow averaging of all brands of a company but provides for averaging only of brands with more than 1% market share."

2.5 In compliance to the above said order, NPPA has re-notified the price of Amphotericin B (Liposomal) 50 mg injection vide NPPA S.O. No. 269(E) dated 16.01.2018 issued by NPPA. The calculation sheet of the above said price was uploaded on the site on 31.01.2018.

2.6 On review of the calculation sheet, company observed that

- (a) NPPA has again considered the PTR of Lambin Injection 50 mg as Rs. 3000/-, instead of our actual PTR of August 2015 i.e. Rs. 3610.90/- per pack.
- (b) NPPA has excluded the products having MAT value of less than 1% market share.

2.7 In view of above, company requested to review of the S.O. no. 269(E) dated 16/01/2018.

### 3. **Comments of NPPA:**

3.1 In this regard, the ceiling price of formulation fixed by NPPA, vide S.O. No. 269(E) dated 16.01.2018 is detailed below:-

Sl. No	Name of the Formulation	Company's Product Composition	Notified Price (Rs)
1	Amphotericin B-Lipid/Liposomal	Amphotericin B (Liposomal) Injection 50mg	3402.55

3.2 While implementing the earlier review order, the matter regarding PTR for the month of August 2015 with respect to the product Lambin injection 50mg of M/s Sun Pharma Laboratories Ltd was referred to Pharmatrac for verification. Pharmatrac stated that this product is a speciality product and traded by different distribution channels. Pharmatrac also stated that the PTR of Rs. 3610.90 as claimed by company is reported only once in August 2015 and the PTR stated by Pharmatrac i.e. Rs 3000 has the highest count.

3.3 In this connection it was decided that the PTR having highest count as per pharmatrac is to be taken for calculation of ceiling price of the formulation. Accordingly, the PTR of Rs. 3000 per pack being the highest count was taken for price calculation and the price of the formulation was changed from Rs 3394.25 per pack to Rs 3402.55 per pack as a result of review.

3.4 It may be noted that the ground raised by the company is not at all new. The same ground was raised in the earlier review petition and has been duly considered by the Authority, as per the review order. A decision has been taken by the Authority by going through all the reports/figures as mentioned in the above para. The petitioner

company cannot file review petition on an issue which has already been considered by the Authority as a result of review order. The petition, therefore, needs to be rejected at the stage of admission itself.

#### **4. Examination:**

4.1 M/s Sun Pharma Laboratories Limited earlier filed a review application on 6.4.2017 against ceiling price fixation of formulation Amphotericin B (Liposomal) Injection 50mg vide SO 788(E), dated 10.3.2017. After examination, DoP issued Review Order No.31015/45/2017-Pricing, dated 16.11.2017 directing NPPA to consider the actual PTR of formulation LAMBIN LYOPHILISED 50 MG INJECTION1 and after verification refix / revise the ceiling price of Amphotericin B (Liposomal) Injection 50mg, on merit. NPPA was further directed to consider PTR of those formulations having MAT value of more than 1% market share.

4.2 In order to implement the DoP's review order, dated 16.11.2017, NPPA referred the matter to Pharmatrac to get confirmation about the PTR of the product of the company, i.e. LAMBIN LYOPHILISED 50 MG INJECTION1 as on August, 2015. Pharmatrac confirmed that the data being reflected is Rs.3000 per pack and the PTR of Rs.3610.90, as claimed by the company, is reported only once in August, 2015. Hence, Pharmatrac captured the PTR of Rs.3000/- has the highest count.

4.3 The matter of considering highest count was deliberated in DoP and it was decided that considering the PTR of the formulations of the company, which is in highest count, is a logical and right decision. In view of this, considering the PTR of Rs.3000/- per pack of LAMBIN LYOPHILISED 50 MG INJECTION1 as on August, 2015 is a right decision, as the said PTR, as per Pharmatrac data, was in high count.

4.4 In view of the above, the request of the company about considering the actual PTR of Rs.3610.90 of their product LAMBIN LYOPHILISED 50 MG INJECTION1 as on August, 2015, cannot be accepted, being on less count.

#### **5. Decision:**

**“Considering the PTR of the formulations of the company, which is in highest count, for ceiling/retail price calculation is a logical and correct decision. Therefore, the request of the company about considering the actual PTR of Rs.3610.90 of their product LAMBIN LYOPHILISED 50 MG INJECTION1 as on August, 2015, cannot be accepted being on less count.”**

Issued on this date, the 26<sup>th</sup> day of June, 2018.

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

Copy to:-

1. M/s Sun Pharma Laboratories Limited, 8-C, 8<sup>th</sup> Floor, Hansalaya 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
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website