

**No. 31015/45/2017-Pricing**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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

**Subject:** Review application of M/s Sun Pharma Laboratories Limited against price fixation of “Amphotericin B (Liposomal) Injection 50mg” vide NPPA order No. S.O. 788(E), dated 10.03.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application, dated 06.04.2017  
2) NPPA notification under review S.O. 788(E), dated 10.03.2017  
3) Record Note of discussions held in the personal hearing held in the matter on 10.10.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharma Laboratories Limited (hereinafter called the petitioner) against notification S.O. No.788(E), dated 10.03.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Amphotericin B (Liposomal) Injection 50mg.

2. The petitioner has contended as under:-

I. Company is aggrieved by the said notification as actual Price to Retail (PTR) of their product Lambin 50 mg injection was captured erroneously in the ceiling price calculation. Further, it is evidenced, that there is deviation from methodology laid down under para 4 of DPCO 2013, in ceiling price calculation.

**II. Grounds:**

(i) NPPA has displayed the draft working sheet of Amphotericin B (Liposomal) 50 mg injection on NPPA website on 17.02.2017. The sheet captured 1pack of the company, viz. LAMBIN LYOPHILISED 50 MG INJECTION 1 whose PTR was erroneously captured in ceiling price calculation. Company had filed the representation dated 01.03.2017 along with necessary documents within 10 working days of draft working sheet displayed on NPPA website. Draft working sheet has captured the PTR as Rs.3000 per pack, while the actual PTR in the month of August was Rs.3610.90 per pack.

(ii) Moreover, 3 specific packs viz. AMPHONEX 50 MG INJECTION 1 of M/S BHARAT SERUMS & VACCINES LTD, and AMFY 50 MG INJECTION 1, AMIFY 50 MG INJECTION 1 of M/S INTAS PHARMACEUTICALS LTD with MAT MS less than 1% have been captured in ceiling price calculation, which is not as per provision of DPCO 2013.

- III. In view of above, Company requested this Department to issue necessary directives to NPPA to recalculate the ceiling price of the captioned formulation.

3. **Comments of NPPA:**

- I. Ceiling price Rs.3328.61/pack is notified for Amphotericin B (Liposomal) injection 50 mg vide S.O. 788(E) dated 10.03.2017 & the same was revised to Rs.3394.25/pack vide S.O. 2059(E) dated 30.06.2017 as per Para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.
- II. The company has stated that correct methodology was not followed in arriving at the ceiling price of Amphotericin B (Liposomal) injection 50 mg. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company submitted representation by stating that their product Lambin Lyophilised 50 mg injection was included in the calculation sheet considering PTR Rs.3000 against the actual PTR Rs. 3610.90/pack in the month of August, 2015. Company also submitted necessary documents in support of their claim.	NPPA examined the representation and documents submitted by the company and send to Pharmatrac for verification of the PTR. It was stated by Pharmatrac that pack under reference is hospital deliver product. Based on stockist feedback, Pharmatrac found that PTR may be 3659. As the price reference is based on the stockist feedback and not the market capture, therefore, representation submitted by the company was not considered by the authority.
2.	Company has also pointed out PTR and MAT value of 3 packs viz. 1. Amphonex 50 mg injection of M/s. Bharat Serum and Vaccines Ltd. 2. Amfy 50 mg injection, and 3. Amify 50 mg injection 1 of M/s. Intas Pharmaceuticals Ltd. was considered by NPPA while calculating the ceiling price of subject formulation. Although, their MAT percentage is less than 1%.	While fixing the ceiling price, the PTR of 3 packs as mentioned by the company was taken based on company wise 1% MAT as per the decision taken in 27 <sup>th</sup> authority meeting to include list of the three alternatives while calculating the ceiling price.

- III. Company has not challenged in any Court in respect of ceiling price fixation for Amphotericin B (Liposomal) injection 50 mg vide S.O. 788(E) dated 10.03.2017.
4. During personal hearing company representative has submitted following:

- The company representative requested the authority to intervene and give necessary directives to NPPA to revise the Ceiling Price of the captioned product because
  - i. Company's representation dated 01.03.2017 was complete in all respect
  - ii. NPPA representative mentioned that company's representation claiming PTR of Rs.3610.90 was not considered in Authority Meeting as PTR of Rs.3659 confirmed by Pharmatrac was based on stockiest feedback and not market capture.
- The company is anyhow claiming lower PTR (Rs.3610.90/-) based on their submitted evidence than confirmed by Pharmatrac (Rs.3659/- ).
- Further, the company representative requested the authority to give necessary directives to NPPA to revise the Ceiling Price after excluding 3 packs (having market share of less than 1%) namely
  - i. Amphonex 50 mg injection of M/s. Bharat Serum and Vaccines Ltd.
  - ii. Amfy 50 mg injection and
  - iii. Amify 50 mg injection 1 of M/s. Intas Pharmaceuticals Ltd.

4.2 NPPA representative stated that they have no further comments in addition to as stated above.

## 5. **Examination:**

In the instant case, the company's contention is that NPPA has taken into account wrong and incorrect PTR/Price of formulation LAMBIN LYOPHILISED 50 MG INJECTION 1 while fixing the ceiling price of the formulation. The company stated that NPPA has captured the PTR as Rs.3000 per pack, while the actual PTR in the month of August was Rs.3610.90 per pack. In support of its claim, the company submitted a copy of letter dated 01.03.2017 containing all necessary information/documents.

5.2 NPPA stated that on receipt of representation from the petitioner company, they got confirmation from Pharmatrac, and Pharmatrac stated that based on stockist feedback, the PTR may be 3659. During the personal hearing, the company submitted that they are however claiming lower PTR, i.e. Rs.3610.90, based on their evidence submitted along with representation, dated 1.3.2017. In view of the above, it is observed that there is a merit in the contention of the company, and NPPA may be 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 50mg, on merit.

5.3 It is also observed from the calculation sheet, that the contention of company's contention that PTR of 3 packs viz. AMPHONEX 50 MG INJECTION 1 of M/S BHARAT SERUMS & VACCINES LTD, and AMFY 50 MG INJECTION 1, AMIFY 50 MG INJECTION 1 of M/S INTAS PHARMACEUTICALS LTD with MAT value of less than 1% market share have been captured in ceiling price calculation, has also got merit.

NPPA has erred in calculating ceiling price of the subject formulation as per para 4 of DPCO, which clearly mentions that medicines having PTR and MAT value of more than 1% market share are to be taken for calculation. In the instant case, the principles applied by NPPA go beyond what is mentioned in DPCO. NPPA has considered the PTR of 3 packs as mentioned by the company, based on company wise 1% market share of MAT value, whereas DPCO does not recognize a company for average PTR but only medicines/formulations. It is observed that the number of formulations which are to be considered having more than 1% market share and number of formulations to be excluded, as per table given below :-

Formulation Name	<u>Number of brands to be considered having more than 1% market share</u>	<u>Number of brands to be excluded having less than 1% market share</u>
Amphotericin B (Liposomal) Injection 50mg.	8	3

5.4 In view of the above, NPPA may be directed to re-fix and re-notify the ceiling price of formulation Amphotericin B (Liposomal) Injection 50mg. by considering the PTR of those formulations having MAT value of more than 1% market share.

**6. Government Decision:**

**“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 50mg, on merit.”**

**“NPPA is further directed to re-fix and re-notify the ceiling price of formulation Amphotericin B (Liposomal) Injection 50mg. by considering the PTR of those 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.”**

Issued on this date, the 16<sup>th</sup> day of November, 2017.

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

To

1. M/s. Sun Pharm Laboratories Limited,  
Sun House, Plot No.201 B/1,  
Western Express Highway, Goregaon (E),  
Mumbai-400063.
2. Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building,  
1, Jai Singh Road,  
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