

No. 31015/18/2018-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 13.02.2018, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Mylan Pharmaceuticals Private 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 price of Amphotericin B Powder-Lipid/Liposomal (Powder for Injection 50mg).

2. The applicant has contended as under:-

2.1 The Applicant is aggrieved by the said Notification, for the following reasons:

(i) Contrary to the provisions of DPCO, 2013, while arriving at the ceiling price, NPPA has considered 'Amphomul'- the brand of Bharat Serums and Vaccines Ltd, twice in the 'Computation Sheet for Calculation of Ceiling Price', at Sr. Nos. 2 and 3.

(ii) The Applicant submits that only the brand "AMPHOMUL 50MG INJECTION 10 ML" mentioned at serial no. 3 should have been considered for price calculation while item at sl. no. '2' ought not to have been considered.

2.2 The Applicant further submits that when the ceiling price of this formulation was notified vide Notification No. S.O. 788 (E) dated 10.03.2017, the said notification was challenged by the Applicant vide its Review Application dated 06.04.2017, on various grounds, inter-alia, those mentioned in paragraph 3 above.

2.3 The said fact regarding double entry of 'Amphomul' was also noted by the NPPA during the personal hearing held on May 30, 2017 and was further recorded in NPPA's Written Submissions.

2.4 The Department of Pharmaceuticals (DoP), after hearing the above mentioned Review Application on May 30, 2017 passed an Order dated September 07, 2017 [No. 31015/43/2017-Pricing] (hereinafter the 'Order').

2.5 However, while disposing the Review Application the Reviewing Authority did not pass any express directions on the grounds raised in paragraph 3 above. Therefore, the Applicant immediately sought further review of the above mentioned Order by filing an application on September 20, 2017 before NPPA (Second Review Application), a copy of which was also submitted to the offices of Department of Pharmaceuticals (DoP).The same was taken on record by both the offices.

2.6 The applicant in the Second Review Application has made submissions to rectify the error relating to the double entry for ‘Amphomul’, at the time of revision- of ceiling price (in pursuance of the Review Application filed by the applicant) of “Amphotericin B Powder for Injection – Lipid Liposomal” by eliminating the duplicate entry of AMPHOMUL and considering the correct number of brands for ceiling the price, which should only be 7 brands instead of 8 brands.

2.7 While the abovementioned Second Review Application was pending for hearing and disposal, the NPPA has revised the ceiling price of the “Amphotericin B – Lipid/Liposomal Powder for Injection 50mg” to Rs. 3402.55 per pack vide notification number S.O. 269(E) dated 16.01.2018.

2.8 Further, as stated in page 11 of the Order -under serial no. 5, the DOP had reportedly issued a letter No. F.No. 31015/44/2016-P1.1 dated 11.7. 2016 (‘Letter’), pursuant to which DOP gave the following directions “NPPA to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceuticals firms. Only after taking into account the comments or any additional data thus received within the given time period, the NPPA shall finalize the Ceiling and the Retail Prices. This issues with the approval of Hon’ble Minister (Chemicals & Fertilizers)”.

However, NPPA failed to place a draft version of the Price Calculation Sheets for the proposed revised price notification on the website of NPPA as indicated in the said Letter, consequently the same error of double entry of ‘Amphomul’ continued, consequently, giving the need for the present Review Application against the Said Notification.

2.9 Being aggrieved by such fixation of ceiling price, the Applicant is therefore constrained to file the present Review Application.

2.10 The Applicant by this Review Application submits that the ceiling price should be fixed after eliminating the duplicate entry of ‘Amphomul’ as mentioned in paragraph 3 and therefore total number of brands for calculation of the ceiling price should be considered as 7 and not 8.

2.11 In view of the abovementioned facts and circumstances, it is therefore most respectfully prayed that only the brand “AMPHOMUL 50MG INJECTION 10 ML” mentioned at serial no. 3 should be considered for price calculation and item at sl. no. ‘2’ must be deleted, and the ceiling price should be re-calculated after rectifying the error of double entry as mentioned herein above.

2.12 The Applicant further submits, pending the disposal of the Review Application, it continues to sell ‘AmBisome’ at a price not exceeding the ceiling price fixed by the **Notification No. S.O. 269 (E) dated 16.01.2018**, in accordance with the provisions of the DPCO, 2013.

3. Comments of NPPA:

3.1 The ceiling price of the subject 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 Powder-Lipid/Liposomal	Powder for Injection 50mg	3402.55

3.2 Grievances of the company and NPPA's reply are as below:

(i) Company's Grievance:

Company stated that NPPA notified the ceiling price of Amphotericin B (Liposomal) Injection 50mg as Rs. 3402.55 per pack vide S.O. 269 (E) dated 16.01.2018 by implementing the petitioner company's review order No. 31015/43/2017-Pricing dated 07.09.2017 and M/s Sun Pharma Laboratories' review order No 31015/45/2017-Pricing dated 16.11.2017.

The company contented that in the earlier review petition they have stated that the product "Amphomul" of M/s Bharat Serum and Vaccine Ltd. was appearing twice (serial No. 2 &3) in the calculation sheet and the same needed to be rectified. However, the Reviewing Authority did not pass any direction in this regard in the earlier review order.

Accordingly, the company requested to re-fix the ceiling price of Amphotericin B Powder-Lipid/Liposomal (Powder for Injection 50mg) by excluding the item mentioned in serial No. 2 i.e. Amphomul of M/s Bharat Serum and Vaccine Ltd.

NPPA's Comments:

The issue regarding appearance of the product "Amphomul" twice in the working sheet was raised in the earlier review application also and considered by DoP. After due consideration, DoP did not pass any order on this issue in the earlier review order. Therefore, the petitioner company cannot file the review on the same issue again and the review petition needs to be rejected on this ground alone at the stage of admission itself.

The ceiling price of Amphotericin B Powder-Lipid/Liposomal (Powder for Injection 50mg) was calculated based on pharmanac data where both the products of M/s Bharat Serum and Vaccine Ltd. were mentioned separately. The petitioner company has not submitted any document to support their contention that both the products of M/s Bharat Serum and Vaccine Ltd reflected in the worksheet are the same. It may also be stated that the concerned company i.e. M/s Bharat Serum and Vaccine Ltd. has not raised any objection on this issue.

It may also be noted that the change in price from Rs 3394.25 per pack to Rs 3402.55 per pack was due to other two parts of the review order No. 31015/43/2017-Pricing dated 07.09.2017 in case of M/s Mylan Pharmaceuticals specifically about **data issue of the product Ambisome of Mylan Pharmaceutical and regarding consideration of medicine /formulation having MAT value of more than 1% of market share** and review order No 31015/45/2017-Pricing dated 16.11.2017 in case of M/s Sun Pharma Laboratories' specifically regarding **consideration of medicine /formulation having MAT value of more than 1% of market share**

(ii) Company's Grievance:

Company also pointed out that NPPA has also not implemented the directions issued by DoP's letter No. 31015/44/2016-PI-I dated 11.07.2016 regarding uploading the draft version of price calculation sheet before revised price notification.

NPPA's Comments:

DoP's letter No. 31015/44/2016-PI-I dated 11.07.2016 is applicable for fixation of ceiling price under NLEM 2015 and the notification S.O. 269(E) dated 16.01.2018 was issued towards implementation of review order. Since it was decided to implement all the review order quickly and preferably within 30 days, the draft work sheet were not uploaded prior to the meeting of the Authority, as it would have taken longer time.

3.3 As per information available in this office no case in respect to S.O. 269 (E) dated 16.01.2018 is filed by the company. DoP is also requested to obtain confirmation on the issue.

3.4 M/s Mylan Pharmaceuticals Private Limited has not submitted form V for the formulation Amphotericin B powder-lipid/liposomal (powder for injection 50mg) notified by NPPA vide SO 269(E) through IPDMS hence ceiling price compliance status cannot be confirmed. Accordingly, DoP is requested to verify the compliance of ceiling price notified by S.O. 269 (E) dated 16.01.2018 in respect of subject formulation from the company by taking verified document from the companies.

4. During the personal hearing, the company representative further stated that –

4.1 The Applicant has sought review under para 31 of DPCO 2013, of Notification No. S.O. 269 (E) dated 16.01.2018 (“Impugned Notification”), fixing the ceiling price for ‘Amphotericin B Powder for Injection – Lipid Liposomal’ at **Rs.3402.55** per 50 mg pack.

4.2 The Applicant, Mylan Pharmaceuticals Private Limited (MPPL) is a company registered in India under the Companies Act, 1956, and is engaged in the import and marketing of drugs in India. The Applicant imports and sells inter-alia, the innovated “Liposomal Amphotericin B” (L-Amb) in India under the innovator brand “AmBisome”, under an exclusive license agreement with the innovator, M/s. Gilead Sciences Inc.

4.3 Vide letter dated 07.03.2018 the applicant was directed to present the case in person on 20.03.2018 at 11:30 am at your good offices. The applicant has made a presentation in person as directed, through its representatives.

Brief Background

4.4 The ceiling price of Amphotericin B formulations was fixed accordingly for the first time in the year 2013 and was revised annually until 2016 as under:

Date of Notification	Notification No.	Ceiling price (Rs./ 50 mg pack)
28.06.2013	S.O. 1912 (E)	4,245.32
28.04.2014	S.O. 1156 (E)	4,513.62

26.02.2015	S.O. 619 (E)	4,687.35
02.03.2016	S.O. 644 (E)	4,560.30
10.03.2017	S.O. 788 (E)	3,328.61
01.04.2017	S.O. 1039 (E)	3,394.25
30.06.2017	S.O. 2059 (E)	3,394.25

4.5 When the ceiling price of this formulation was notified vide Notification No. S.O. 788 (E) dated 10.03.2017, the said notification was challenged by the applicant on various grounds vide a Review Application dated 06.04.2017.

4.6 It was one of the grounds in the abovementioned Review Application that the “Amphomul” has been considered twice

4.7 The said statement of fact regarding “Amphomul” was also noted by the NPPA during the personal hearing held on 30.05.2017 and was further also recorded in NPPA’s Written Submissions at Serial No. 6 under ‘Part B (Para-wise Comments)’.

4.8 The Department of Pharmaceuticals (DoP), after hearing the abovementioned Review Application on 30.05.2017 passed an Order dated September 07, 2017[No. 31015/43/2017-Pricing]. The fact mentioned in paragraph 6 above is duly recorded in the Order (Pg 12).

4.9 However, while disposing the Review Application the Reviewing Authority did not pass any direction on the ground of double entry of “Amphomul”. Therefore, the Applicant immediately sought further review of the abovementioned Order by filing an application on 20.09.2017, before NPPA. A copy was also submitted to the offices of Department of Pharmaceuticals (DoP). The same was taken on record by both the offices.

4.10 The applicant vide abovementioned application had made submissions to rectify the error relating to the double entry for ‘Amphomul’, at the time of re-fixation of ceiling price of “Amphotericin B Powder for Injection – Lipid Liposomal” by eliminating the duplicate entry of AMPHOMUL and considering the correct number of brands for ceiling the price, which should only be 7 brands instead of 8 brands.

4.11 The applicant has also filed additional documents for rendering assistance to NPPA for the purpose of arriving at the correct PTR.

“Amphomul” should be considered only once for working of ceiling price vide order dated 16.01.2018

4.12 While the Review Application dated 20.09.2017 is pending for hearing and disposal, the NPPA has revised the ceiling price of the “Amphotericin B – Lipid/Liposomal Powder for Injection 50mg” to Rs. 3402.55 per pack vide notification number S.O. 269(E) dated 16.01.2018.

4.13 “Amphomul” has been considered twice in the working sheet (SN. 2 & 3 – Amphomul) which makes the total number of brands as 8.

4.14 Bharat Serum has written a letter to AWACS on 19.03.2018 for correction of double entry of its brand 'Amphomul' in the working of ceiling price (Vide S.O. 269) of Amphotericin B Powder Lipid/Liposome. It states that Bharat Serum had only one brand in Auguts'15 and the PTR of the product in August'15 was Rs.1096.38. It has therefore requested AWACS to correct the database by deleting the wrong entry of the product with PTR of Rs. 1043.81(SN.2).

4.15 The entry of "Amphomul" at SN. 2 should be eliminated and only the entry at SN. 3 should be considered for the working of ceiling price.

4.16 After eliminating the entry of "Amphomul" at SN. 2 the ceiling price should be re-fixed by only considering the 7 brands.

4.17 As on date we are selling our product "AmBisome" based on the ceiling price (Rs. 3,394.25) notified by NPPA vide S.O. dated 01.04. 2017. Form-V for this price has been filed by Mylan on 09.04.2017. The price of "AmBisome" as on date is based on the ceiling price (Rs. 3,394.25) not exceeding the ceiling price (Rs.3402.55) fixed vide S.O. dated 16.01.2018 which is in accordance with the Paragraph 31 of The Drugs (Prices Control) Order, 2013. We are in process of revising the price in accordance with the revised ceiling price notified on 16.01.2018. Mylan will submit the Form-V within 15 days of implementation of the ceiling new price.

4.18 In view of the above mentioned facts and circumstances, company prayed that the application may be allowed in terms of its prayers.

5. NPPA in its reply has stated that NPPA has already sent the comments as incorporated above. With respect to para 12 of the record note of discussion in the personal hearing stated by the company, NPPA stressed on the fact that the notification 269(E), dated 16.1.2018 was issued towards implementation of the review order issued by Deptt. of Pharmaceuticals for M/s Mylan Pharmaceuticals (Review order no. 31015/43/2017-Pricing, dated 07.9.2017) and M/s Sun Pharma Laboratories Ltd. (Review Order no. 31015/45/2017-Pricing dated 16.11.2017).

6. Examination:

The applicant has challenged the NPPA Order S.O. 269(E), dated 16.01.2018 for price fixation of their formulation **Amphotericin B Powder - Lipid Liposomal (Powder for Injection 50mg)** on the ground that NPPA has erred by considering the PTR of 'Amphomul' – the brand of Bharat Serums and Vaccines Ltd. twice in the computation sheet for calculation of ceiling price of Amphotericin B 50mg Powder for Injection- Lipid/Liposomal.

5.2 The applicant earlier filed the review application on 6.4.2017 against the price notification SO 788(E), dated 10.3.2017 for the same formulation. In that application, in addition to other grievances, company also raised the issue of considering twice the data of Amphomul 50 mg injection 10 ml of M/s Bharat Serums and Vaccines Ltd., while calculating the ceiling price of the subject formulation. However, at that time, the applicant did not submit any documentary proof in support of its claim. Therefore, the same request was not considered.

5.3 In the present application, during the hearing, in support of its claim, the applicant submitted copy of letter, dated 19.3.2018 of M/s Bharat Serums and Vaccines Ltd., addressed to AIOCD AWACS (Pharmatrac) to the effect that in August, 2015, the company had just one brand "AMPHOMUL 50mg Injection 10ml and the same is continued now also. The company,

M/s Bharat Serums and Vaccines Ltd., further requested Pharmatrac to correct their database by deleting the wrong entry of the product with PTR of Rs.1043.81. The company also addressed the same letter to NPPA.

5.4 Since, the applicant has now submitted documentary proof in support of its claim, NPPA needs to be directed to examine the documentary proof submitted by the applicant company in support of its claim of data of AMPHOMUL brand of M/s Bharat Serums and Vaccines Ltd., cross-check from Pharmatrac, and after verification, revise the ceiling price of Amphotericin B Powder - Lipid Liposomal (Powder for Injection 50mg), on merit.

6. **Decision:**

“NPPA is hereby directed to examine the documentary proof submitted by the applicant company in support of its claim of data of AMPHOMUL brand of M/s Bharat Serums and Vaccines Ltd., cross-check from Pharmatrac, and after verification, revise the ceiling price of Amphotericin B Powder - Lipid Liposomal (Powder for Injection 50mg), on merit, within a period of thirty days of the issue of this order.”

Issued on this date, the 8th day of June, 2018.

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

Copy to:-

1. M/s Mylan Pharmaceuticals Private Limited, No.32/1 & 34/1 to 4, 7th to 12th Floor, Prestige Platina, Block 3, Kadubesanahalli Village, Varthur Hobli, Outer Ring Road, Bangalore East Taluk, Bengaluru-560 087.
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