

No. 31015/33/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan, New Delhi-110001

ORDER BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s. Lifecare Innovations Pvt. Ltd. against fixation/revision of retail price of scheduled medicine “Amphotericin B injection (50 mg)” vide NPPA notification S.O. No. 1912(E) dated 28/6/2013 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant’s Review application dated 10.7.2013
 2) NPPA notification under review S.O. No. 1912(E) dated 28/6/2013
 3) Record Note of discussions in the personal hearing held on 13.6.2013
 in the matter

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 1912(E) dated 28/6/2013 fixed/revised retail price of scheduled formulation “Amphotericin B injection (50 mg)” under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/s. Lifecare Innovations Pvt. Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 10.7.2013 under para 31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 1912(E) dated 28/6/2013fixing ceiling price of scheduled formulation “Amphotericin B injection (50 mg)” under DPCO, 2013.

3. The grievance of the Petitioner raised in their review applications dated 10.7.2013 was sent to NPPA and the comments of NPPA received thereon, were given to the Petitioner through the record note of discussions held in the hearing on 13.6.2013. Record notes of discussions are made integral part of the review order. After considering the comments of NPPA, the Petitioner has raised the following points, on which comments were given by NPPA representative during the hearing and Department’s comments on the issue is recorded subsequently against each point.

Petitioner: The petitioner representative mentioned that the scheduled formulation i.e. Amphotericin B injection 50 mg is mentioned at Sl. No. 6.3.1 of Schedule I of the DPCO 2013. The data used by NPPA includes Liposomal Amphotericin B and lipid formulation of Amphotericin B, Liposomal and lipid formulations are wrongly included

in the price fixation exercise. If the right formulation is used the ceiling price of Rs.4245.32 will come down to approximately Rs.400 only. While the Liposomal and lipid formulations will be out of the price control net, Liposomal and lipid formulations are different products and cost wise they vary substantially i.e. Rs.400 and Rs.8000. Clubbing dissimilar products is not in the interest of industry and research and ultimately the patient. The company representative further mentioned that no Government document says that Amphotericin B injection is Lyposomal Amphotericin B injection.

NPPA: NPPA representative mentioned that Amphotericin B injection 50 mg per vial is a scheduled drug and the price has been notified by NPPA after considering the information provided by IMS Health as per provision of DPCO. This formulation is delivered in dry powder injection. Lyophilized product is allowed also with the lipid used as a drug carrier in the medicine. The NPPA representative mentioned that cost wise and technically these products are different being the biological products. If ceiling price is changed or revised there will be a funny situation in the market as Amphotericin B injection 50 ml. will be under price control while lyophilized formulation with lipid carrier will go out of price control.

Department's comments:

4. The only technical expert in the Ministry Shri V.K.Tyagi was associated with all the hearings. As Shri Tyagi was on long leave on medical grounds there was no technical expert from the Department. NPPA representative has himself agreed that cost wise and technically these products are different being the biological products. Moreover as per the cost structure of the data used by NPPA the variation in prices of Amphotericin B, Liposomal Amphotericin B and lipid formulations of Amphotericin B are in the range of Rs.211.49, Rs.5142 and Rs.2300. The petitioner representative also mentioned that their market share of Amphotericin B is substantial but their retail sales are insignificant. IMS does not capture their data because they were not registered with IMS.

5. In the meanwhile the matter was put up to the then Hon'ble Minister (I/c), C&F wherein it was decided to refer the matter to the technical committee. The technical committee after considering presentation given by the company in its meeting held on 7.1.2015 recommended that liposomal form of Amphotericin B injection is different from the conventional Amphotericin B injection in respect of R&D, technology, manufacturing process, etc. and, therefore, deserved to be separately categorized

6.. The Technical Committee has recommended that Liposomal form may be categorized separately. However, despite findings of the Technical Committee, differential pricing cannot be done on the basis of existing provisions of DPCO. The DPCO 2013 works on a market based price concept where intermediate processes, cost and other technical considerations have not been taken into account and only the market price has been taken as the sole criteria for price fixation.

07. Scheduled I of the DPCO has included the NLEM 2011 which does not provide for different categorization of Liposomal form of Amphotericin B Injection.

08. Even though the Technical Committee has felt that a case is made out for separate categorization for Liposomal form, it is not permissible within present framework of the DPCO. Thus the review application cannot be accepted and ought to be rejected. However, since on the basis of recommendations of the Technical committee it appears to be a genuine case which deserves differential prices, clarification/amendment/footnote in Schedule I on the basis of a consolidated proposal from NPPA with all supporting documentation could be considered separately. This process would, however, be separate from the review application which is proposed to be rejected for the reasons mentioned above.

09. Based on the above and other documents on record, the Government has decided as under:

“In view of the above, the review application of the petitioner stands rejected.”

Issued on this day of 18th June, 2015.

(A.K. Sah)
Under Secretary to the Govt. of India
For and on behalf of the President of India

To

1. M/s Lifecare Innovations Pvt.Ltd.
B-589, Sushant Lok Phase I
Gurgaon-122009
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. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. Technical Director, NIC with the request to upload the review order on the Department's website

