No. 31015/44/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

……..

B Wing, Janpath Bhavan, New Delhi-110001

O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s. Panacea Biotech 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 23.8.2013
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 18.9.2013 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. Panacea Biotech (hereinafter referred to as the Petitioner) submitted review application dated 23.8.2013 under para 31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 1912(E) dated 28/06/2013 fixing retail price of scheduled formulation "Amphotericin B injection (50 mg)" under DPCO, 2013.

3. The grievance of the Petitioner raised in their review applications dated 26.7.2013 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 18.9.2013. 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 NPPA has mixed 2 different products of Amphotericin B i.e. the conventional and the Liposomal formulation. As per the company representative the Liposomal formulation of Amphotericin B was technology licensed by the Deptt. of Biotechnology. Range

of price mixture taken by NPPA is from Rs.211 to Rs. 8666 which may not evidently be for the same product and in fact it is not the same product. The petitioner representative mentioned that it will be appropriate to seek advice of Deptt. of Biotechnology and Department of Scientific and Industrial Research (DSIR) in the matter as IMS Health may not be technically competent to give advice on whether Liposomal and the conventional forms to be treated as the same.

NPPA comments: NPPA representative mentioned that they fixed the ceiling prices on the basis of description given in the NLEM and also as per the data received from IMS Health. NPPA representative also mentioned that submission of the company is under examination by IMS Health for which a reply is awaited.

4. Department of Pharmaceuticals had received same point for consideration in another review application of M/s Lifecare, Gurgaon. It was decided to seek the comments of DCGI on whether the Amphotericin B injection included Liposomal Amphotericin B and lipid formulation of Amphotericin B. This Department received no reply from DCGI.

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.

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.

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

8. 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.

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 date , 2015.

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

To

1. M/s Panacea Biotech
B-1 Extension/A-27, Mohan Co.op. Industrial Estate
Mathura Road
New Delhi-110044

2. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001

Copy to :

3 PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.

1. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
2. Technical Director, NIC with the request to upload the review order on the Department's website