

**No. 31015/56/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s Biological E. Limited against price fixation of their formulation "Snake Venom antiserum – Soluble/Liquid Polyvalent Inj." vide NPPA order No. S.O. 1334(E), dated 27.04.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 12.05.2017
2) NPPA notification under review S.O. No.1334(E), dated 27.04.2017
3) Record Note of discussions held in the personal hearing on 22.08.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Biological E. Limited (hereinafter called the petitioner) against notification S.O. No.1334(E), dated 27.04.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Snake Venom antiserum – Soluble/Liquid Polyvalent Inj.

2. The petitioner has contended as under:

(i) Company manufactures Snake Anti-Venom Serum (ASVS) - soluble / liquid polyvalent format (pack size is 10 ml). On the basis of the directions passed in a review order by the Department of Pharmaceuticals vide letter no. 31015/45/2014 P.I. in respect of SO 2251(E) dated 22-7-2013, M/s National Pharmaceutical Pricing Authority (NPPA) had fixed the ceiling prices separately for (1) Specific Anti-Snake Venom - injection Polyvalent Solution and (2) Specific Anti-Snake Venom Lyophilized polyvalent Serum.

(ii) Company submitted that NPPA has displayed draft computation of ceiling price calculation sheet proposed to revise the ceiling price fixed on 25th March 2015.

(iii) On going through the draft calculation sheet, Company noticed that there is an error apparent on the face of the record. NPPA has taken Rs. 265.90 as PTR of their product - Anti-Snake Venom Injection of 10 ml., which is grossly erroneous.

(iv) Company submitted their objection to NPPA informing the mistake that has crept in the draft calculation sheet. They also enclosed copy of invoice of August 2015 and also summary of August 2015 invoices. The correct PTR of their product as on August 2015 was Rs.404.08. Hence, the ceiling price determined vide reference cited above at Rs.351.44 is grossly erroneous and liable to be set-aside.

(vii) In view of above, company requested this Department to direct NPPA to re-determine the ceiling price for snake venom anti serum-soluble / liquid polyvalent.

3. Comments of NPPA:

Ceiling price Rs. 351.44/10 ml pack and the same was revised to Rs. 337.05/10 ml pack vide S.O. 2058(E) dated 30.06.2017 as per Para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

3.2 The company has stated that correct methodology was not followed in arriving at the ceiling price of anti-Snake venom. 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 has stated that NPPA has displayed draft computation of ceiling price calculation sheet proposed to revise the ceiling price of anti-Snake venom. NPPA has taken PTR Rs.265.90 for their product Snake Anti-venom injection 10 ml, this is not correct. Company has also stated that PTR of their product was never Rs. 265.90 from the year 2011. Company submitted their objection to NPPA informing the mistake that has crept in draft calculation sheet and also submitted copy of invoice of August 2015 and also summary of the August 2015 invoices.	The statement of the company is factually incorrect, NPPA has not displayed the draft computation of ceiling price calculation sheet in respect of S.O. no. 865 (E) dated 25.03.2015 and the draft computation sheet for fixing the ceiling price under NLEM, 2015 was uploaded on 27.02.2017. However, NPPA did not consider the representation of M/s. Biological E. Ltd since it is not as per OM 8(34)/2014/Div.II/NPPA dated 07.02.2017. NPPA notified ceiling price Rs. 351.44 for snake venom antiserum soluble / liquid / polyvalent 10 ml pack considering the data provided by AIOCD-AWACS for the month of August, 2015. The PTR Rs. 404.08 for snake anti-venom injection 10 ml of M/S Biological E. Ltd was not considered by NPPA as the data/supporting document submitted by company was not in line with OM no. 8(34)/2014/Div.II/NPPA dated 07.02.2017 and their IPDMS compliance was Zero as on 22.04.2017.
2.	Company reiterated that NPPA is not applying logic to arrive ceiling price as DPCO guidelines in spite of their poor communication. Company fails to understand how NPPA has arrived PTR at Rs.265.90 when the actual PTR of their product is Rs.404.08. As per company claim, the PTR of their product as on August 2015 is Rs. 404.08. Hence, the ceiling price determine vide reference cited above at Rs.351.44 is grossly erroneous and liable to be set-aside.	

3.	Company has further stated that their entire data is available with NPPA in IPDMS Form and hence NPPA may be directed to re-determine the ceiling price for snake venom ant - serum soluble/liquid/ polyvalent.	
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3.3 Company has not challenged in any Court in respect of ceiling price fixation for anti-Snake venom vide S.O. 1334(E) dated 27.04.2017 respectively.

4. During the personal hearing the representatives of the company submitted relevant data in support of their claim that the price calculation for arriving at the ceiling price (CP shown Rs.351.44/10ml liquid vial) is wrong. The company representative requested for revised ceiling price based on August, 2015 data.

4.2 NPPA representative submitted that they may examine the matter on submission of relevant documents by the petitioner company.

5. Examination:

The petitioner company, in its review petition, stated that they had represented against the draft working sheet. However, NPPA did not consider the representation of the company as the data/supporting documents submitted along with representation was in line with the requirement.

5.2 During the personal hearing, the petitioner company submitted documentary proof in support of their claim that the correct of PTR of their formulation Snake Anti-venom injection 10 ml is Rs.404.08 instead of Rs.265.90 considered by NPPA.

5.3 In view of the above, the hearing authority is of the opinion that NPPA may be directed to examine the relevant documents/information furnished by the petitioner company, and after verification, to re-fix the ceiling price of Snake Venom antiserum – Soluble/Liquid Polyvalent 10 ml, on merit.

6. Government Decision:

“NPPA is hereby directed to examine the relevant documents/ information furnished by the petitioner company, and after verification, to re-fix the ceiling prices of Snake Venom antiserum – Soluble/Liquid Polyvalent Inj., on merit.”

Issued on this date of 30th day of October, 2017.

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

To

1. M/s. Biological E. Limited ,
Plot No.623 – H, Road No.35,
Jubilee Hills,
Hyderabad-500 033.
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. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department's Website.