

**No. 31015/24/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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B Wing, Janpath Bhavan,  
New Delhi 110 001

**Subject: The review application of M/s Premium Serums & Vaccines Pvt. Ltd. dated 16/04/2015 under para 31 of DPCO against NPPA order No. S.O. 838(E) dated 25/03/2015 for price fixation of “Specific Anti-Snake Venom Lyophilized Polyvalent Serum” under DPCO 2013.**

**Ref: 1) Review application dated 16.04.2015**  
**2) NPPA notification under review S.O. No.838(E) dated 25.3.2015**  
**3) Record Note of discussions held in the personal hearings held in the matter on 1.6.2016.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Premium Serums & Vaccines Pvt. Ltd. (hereinafter called the petitioner) against notification S.O. No.838(E) dated 25.03.2015 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of “Specific Anti-Snake Venom Lyophilized Polyvalent Serum”.

2. During the personal hearing held on 1.6.2016, the petitioner has contended as under:

- NPPA’s price notification of 2015 for Anti-snake Venom Serum was based on average price of existing manufacturers in 2012. It was made applicable in March, 2015 for lyophilized products. They submitted that their company started selling this product in August, 2014 onwards. They submitted that the old companies had already recovered their capital investment in the preceding years whereas, being a new company, their cost of establishment and the cost of production is high. Due to enforcement of new price notification, the difference between pre-notification price and post-notification price is almost 40% reduction in MRP. This has resulted into drastic reduction in the revenue generation by the company than projected;
- that almost 80% of the requirement is of Government hospitals on tender basis. To qualify in the tender, the company should have minimum turnover of about Rs.25 crores. Due to reduction in price, their turnover has got affected and they are not able to participate in the Government

tenders. In the present circumstances, the company has to sell all products in the trade business where the net realization is low as compared to tender business;

- that this particular product is animal derived, produced from the blood of horses. The company has to maintain large number of horses and look after them during the manufacturing process as the horses have to be progressively injected with snake venom. The activity continues every day throughout the year. Therefore, it requires more number of persons to take care of horses round the clock. There is lot of variability in the production process and no guaranteed yield can be predicted. However, manufacturer has to ensure production of consistent quality by overcoming all the variables. The entire process is capital as well as labour intensive with very high component of fixed cost. Therefore, the company representatives requested that different pricing mechanism may be adopted, particularly, for this product, considering the tedious manufacturing process and the animal welfare issues involved in the manufacturing; and
- that keeping in view the perpetual shortage of this life saving product, the new entrants like their company, will not enter in this field unless the prices are sustainable on long term basis.

During the hearing, the Petitioner Company also submitted that being a new entrant into the market, (as their product was launched during August 2014 only) they are at a disadvantage, vis-a-vis the existing manufacturers who have been in the market for a considerable period. The Petitioner has also pointed out that this product is meant for the treatment of snake bites which is very widespread in rural areas. It is a fact that more than 50,000 deaths are reported due to snake bite in the country, especially in the monsoon seasons. For many decades this product continues to be in short supply with regular and sporadic reports from various quarters about acute shortage of this Specific Anti-snake Venom Lyophilised Polyvalent Serum injection. **Such a situation is least conducive to encourage any new entrant to contemplate entry in the market mainly due to very high investment in rearing large number of horses and uncertainties and problems associated with agro-based activities.**

The development of antibodies is based upon the species of indigenous varieties of snakes. It was reported that due to this reason, in spite of chronic shortage of the product, it is neither feasible to be imported nor practicable on account of variation in the species prevalent in other countries. **Accordingly, the petitioner requested for differential treatment to the products emanating from such high capital and labour intensive enterprises.**

The contention of the NPPA has been that the provisions of the existing DPCO **do not provide any flexibility** or differential pricing mechanism in such cases. Accordingly, there is no ground for reconsideration of the prices notified by it.

During the discussion, it was pointed out that the product under reference is derived through biological process involving (i) Collection/procurement of Snake Venom, (ii) Growth of antibodies in the blood of horses through progressively injecting measured and controlled doses of Snake-venom followed by (iii) Extraction/harvesting antibodies from horse blood for further processing and (iv) formulation into the end product. The yields and quality of products are prone to variations due to various factors. On these grounds the applicant requested for considering this type of biological products **for some facilitation mechanism and incentivisation to encourage indigenous production of the Anti-snake venom serum.**

### **3. NPPA's submission:**

NPPA's representative submitted that this product is covered u/s 4.2.2. and 19.2.2 of schedule I of DPCO 2013 and NPPA has fixed the ceiling price of this formulation as per para 4, 10, 11, 14 & 16 of DPCO,2013, as in case of other scheduled formulations. There is no separate provision/ground in the DPCO, 2013 to consider the request made by the company. Therefore, the company is advised to follow the existing price.

### **4. Examination:**

Based on the submissions of Petitioner M/s Preium Serums and Vaccines Pvt. Ltd., Pune, and NPPA, the following position emerged:

The Company representative mentioned that the notification does not specify the composition. The composition in each 1 ml of snake venom Antiserum neutralizes not less than 0.60 mg of Indian Cobra Venom, 0.45 mg of common Krait venom, 0.60 of Russell's viper venom, 0.45 mg of saw scaled viper venom. The company representative mentioned that the specific composition should be notified to bring clarify.

It may be seen that entries at S.NO.4.2.2 and 19.2.2 of Schedule I of DPCO, 2013, does not give the break up of neutralization dose. Therefore, the action of NPPA to fix the price is in order.

The company representative has mentioned that the average price of May, 2012 was considered by NPPA while WPI for the year 2012 given in 2013

has not been given. In this point also, company has no merit as DPCO 2013 came into effect in May, 2013 and upto May 2013, the prices as prevailing in the market before DPCO 2013 were applicable.

The company mentioned that their manufacturing process of anti-snake venom is different from the chemical products. They are new manufacturer and, therefore, their pricing should be treated differently. Since, the criteria for fixing the ceiling/retail price under DPCO 2013 is market based instead of cost based, there is no provision for differential pricing. Hence, there is no merit in the point raised by the petitioner.

**5. Decision of the Government:**

In view of the above facts, review application of the company stands rejected.

Issued on this date 30<sup>th</sup> of June, 2016.

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

**To**

- 1. M/s. Premium Serums & Vaccines Pvt. Ltd.,  
406, 'B' Wing,  
High Rose Co-op. Housing Society  
92, Dixit Road Extension  
Vile Parle (E), Mumbai-400 057.**
- 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**