

**No. 31015/27/2017-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 22.02.2017, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Serum Institute of India Pvt. Ltd. (hereinafter called the applicant) against notification S.O. No.248(E), dated 24.01.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Tetanus Toxoid Vaccine (Injection).

2. The applicant has contended as under:-

**Background:**

2.1 NPPA first fixed the Ceiling Price of Tetanus Toxoid Vaccine (Injection) vide Notification S.O. No. 1673(E) dated 14.06.2013 said to have been issued under Para 4, 11, and 14 of the DPCO. *Vide* the said Notification, the NPPA declared that the price for 'each pack' of Tetanus Toxoid to be Rs.10.29. All manufacturers of Tetanus Toxoid, including the applicant, implemented the ceiling price of Rs.10.29 for 0.5ml ampoule of Tetanus Toxoid. Company stated that all manufacturers in India manufacture and sell only 0.5ml ampoules and 5ml vials. No manufacturer in India manufactures or sells a 1 ml vial of Tetanus Toxoid. Moreover, an ampoule is a single dose pack sold to consumers directly from retail chemists while a 5ml vial is a multi-dose pack sold mostly to large institutions such as hospitals.

2.2 Subsequently, the NPPA issued Corrigendum S.O.No. 431(E) dated 17.02.2014, through which it modified the meaning of 'each pack' referred to in the Notification to read as '1 ml'. As per the erroneous understanding of the NPPA, the pro-rata rate of a 0.5ml ampoule of Tetanus Toxoid vaccine would therefore be Rs.5.15.

2.3 The industry, including their company, made a collective representation to the NPPA in 2014. No response was received from the NPPA. The basic errors in the calculations were:

- (i) Clubbing of the Price to Retailer (**PTR**) of 0.5ml ampoules with PTRs of 5 ml vials; and
- (ii) Calculation of a ceiling price of 1ml pack and applying a pro-rata price for 0.5 ml ampoules.

2.4 In this regards the Hon'ble Delhi High Court in Writ Petition bearing title and number, *M/s Biological E Ltd. & Anr. v. NPPA & Anr., W.P (C) 3126 of 2015* was pleased to stay the operation of, inter alia, the SO No. 1673(E) dated 14.06.2013 and the Corrigendum.

2.5 It is also pertinent to note that as per the decision of the Hon'ble Delhi High Court in *Reckitt Benckiser vs. Union of India & Ors., W.P.(C) 7705 of 2013*, **judgment dated 10.07.2015, the NPPA does not have the jurisdiction to fix the ceiling price of Tetanus Toxoid vaccine for the reason that Para 4 of the DPCO empowers the NPPA to fix a ceiling**

**price only for scheduled formulations of specified strength and dosages as specified under the First Schedule.** As no strength or dosage is fixed for Tetanus Toxoid vaccine, the NPPA does not have the jurisdiction to fix the ceiling price of the same, and as such the Impugned Notification is void ab initio.

2.6 In 28.04.2014, the NPPA issued SO 1156(E) fixing the ceiling price of Tetanus Toxoid vaccine at Rs.10.94 per 1ml. Subsequently, on 26.02.2015, the NPPA issued S.O. 619(E) fixing the ceiling price at Rs.11.36 per 1ml, and vide S.O. 644(E) dated 02.03.2016, the price was fixed at Rs.11.05 per 1ml. It may be noted that the said notifications were pursuant to the annual revision based on the Wholesale Price Index (**WPI**) as per the provisions of Para 16 of the DPCO and did not involve a fresh calculation of the ceiling price. On 12.08.2016, the NPPA issued a draft version of the proposed calculation sheets for revised/ notified ceiling price/ retail of Tetanus Toxoid 0.5 ml and 5.0 ml formulations (**'Calculation Sheet'**). *Vide* their letter dated 23.08.2016, they had highlighted that the proposed price calculation for the revision/ notification of the ceiling prices of Tetanus Toxoid is not as per the stipulated procedure under the DPCO, 2013 as (a) PTR of all players having over 1% market share had not been considered, b) The ceiling price has been compared with derived PTR which was worked out on pro-rata basis.

2.7 **It is pertinent to note that Explanation No. 6 inserted vide S.O. 701(E) dated 10.03.2016 amending the First Schedule of the DPCO reads as under: “For injectable preparations, the pack size (single and multi-dose packs) has not been mentioned. It is suggested that the single and multi-dose pack sizes be considered as separate entities for purposes such as procurement/pricing etc.”**

2.8 Subsequently a Committee of Experts was formed by Department of Pharmaceuticals as per the provisions of Para 11(4) of the DPCO to address the issue regarding single and multi-dose usage based on therapeutic rationale. As per the Minutes of the 3<sup>rd</sup> Meeting of the Committee held on 28.12.2016, the Committee had recommended for fixation of separate prices under Para 11(3&4) of DPCO 2013 for single and multi-dose formulations.

2.9 In response to NPPA's letter dated 09.12.2016, company vide their letter dated 28.12.2016 highlighted certain anomalies in the working of the ceiling price of Tetanus Toxoid, including but not limited to (a) that the NPPA ought to have notified a ceiling price for 0.5 ml and not 1 ml; (b) that the price of single dose and multiple dose vaccines do not move in linear progression as purported to have been done by the NPPA. Further, *vide* the instant letter, attention was also invited to the anomalies in the office memorandum dated 12.08.2016, issued by the NPPA, wherein draft price calculations sheets were published for Tetanus Toxoid. *Vide* its letter dated 16.01.2017, the NPPA requisitioned information from the company which included PTR and Moving Annual Turnover (**MAT**) data along with supporting documents such as copies of sample invoices to retailers, summary of all invoices issued during the month of August 2015 and required the said information to be furnished by 23.01.2017. This letter was received by company on 23.01.2017. The said data was furnished by company vide Letter dated 25.01.2017.

2.10 Without awaiting the response to its letter dated 16.01.2017, the NPPA on 24.01.2017 issued Notification S.O. No. 248(E) fixing the ceiling price of Tetanus Toxoid injection for each pack (0.5 ml) at Rs.5.53 and 5.0 ml at Rs.24.41 (**Impugned Notification**). Immediately after learning that the Impugned Notification was already issued, they have sent a letter dated 27.01.2017 to NPPA highlighting the anomalies in the working.

## **Grounds of Review:**

### **A. NPPA does not have the power to fix the ceiling price of Tetanus Toxoid vaccine**

2.11 As referred to above, under Para 4 of the DPCO, the NPPA only has the power to fix the ceiling price for Scheduled Formulations of specified strength and dosages as specified under the First Schedule. As no strength or dosage is fixed for Tetanus Toxoid vaccine, the NPPA does not have the jurisdiction to fix the ceiling price of the same, and as such the Impugned Notification is void ab initio. The Hon'ble Delhi High Court has affirmed this position in **Reckitt Benckiser vs. Union of India & Ors., W.P.(C) 7705 of 2013**, judgment dated 10.07.2015, where the Court held that as the strength or dosage of condoms had not been specified in the First Schedule, the NPPA would not fix the ceiling price of the same.

### **B. Pro-rata pricing is not applicable to injectables**

2.12 It is submitted that the NPPA has again committed the error of applying pro-rata pricing while fixing the ceiling price of 0.5 ml ampoules of Tetanus Toxoid. As per the Calculation Sheet of the NPPA, the price 'per unit considered' has been taken as 4.90 for 0.5ml ampoules. This has been done by evidently treating a 'Unit' as '1 ml' rather than 0.5 ml based on earlier erroneous calculation of 2013 as adjusted with the WPI for the years 2014 and 2015. This is a gross error committed by the NPPA and in violation of Explanation 6 of the First Schedule, Para 11(3) of the DPCO, and the recommendation of the Committee of Experts.

2.13 It is submitted that pro-rata pricing is only applicable to tablets and capsules and not to injectables. Given that the ceiling price of 0.5 ml ampoule has to be set separately as per the above provisions, the NPPA cannot purport to calculate the price of a 1 ml pack.

2.14 No company in India manufactures or sells a 1ml pack of Tetanus Toxoid vaccine. Hence, the NPPA has erred in considering the PTR for 1ml pack rather than 0.5ml.

2.15 It may be noted that the same issue arose with respect to the S.O. No. 1673(E) dated 14.06.2013 read with the Corrigendum that is subject matter of the challenge currently pending before the Hon'ble Delhi High Court in **W.P (C) 3126 of 2015**, which is pending final adjudication before the Hon'ble Court.

2.16 The gross error is all the more noticeable as a similar approach does not appear to have been followed by the NPPA while fixing the ceiling price of 5ml vials of Tetanus Toxoid vaccine as can be seen from the Calculation Sheet.

### **C. NPPA has not considered the other manufactures of Tetanus Toxoid vaccine**

2.17 It is submitted that the major manufactures of Tetanus Toxoid vaccine in India are:

- (i) Biological E Ltd.
- (ii) Serum Institute of India Ltd.
- (iii) Dano Vaccines and Biologicals Pvt. Ltd.
- (iv) Indian Immunologicals Ltd.
- (v) Bio Vaccines Pvt. Ltd.

All the said manufactures market and sell both 0.5ml ampoules and 5ml vials of Tetanus Toxoid vaccine.

2.18 However, while calculating the ceiling price of 0.5ml ampoules, the NPPA has not taken into account data of Dano Vaccines nor that of Bio Vaccines Pvt. Ltd. This is contrary to the mandate of Para 4 of the DPCO which requires that all brands and generic versions of the medicine having 1% of more of the total market turnover on the basis of the MAT of that medicine need to be taken into account. Similarly, in the case of 5ml vials, the NPPA has not taken into account data of Indian Immunologicals Ltd., or Bio Vaccines Pvt. Limited.

**D. The NPPA has not taken into the relevant data into consideration**

2.19 Para 9(3) of the DPCO mandates that the NPPA take into account the data for the month of May 2012 when fixing the ceiling price of a scheduled formulation. However, the NPPA has taken the data for the month of August 2015 instead.

2.20 Assuming that August 2015 data is the relevant data for consideration, it is submitted that the NPPA has not taken into account the data as submitted by us while fixing the ceiling price. This is evident from the fact that vide Letter dated 16.01.2017, the NPPA requisitioned information from the us which included PTR and MAT data (along with supporting documents) for the month of August 2015 and required the said information to be furnished by 23.01.2017. This letter was received by company on 23.01.2017.

2.21 The said data was furnished by company vide Letter dated 25.01.2017. However, the NPPA issued the Impugned Notification on 24.01.2017. It is therefore clear that the NPPA has followed an arbitrary and unjustifiable process in gathering the relevant data and it has resulted in not considering the data submitted by the companies.

**E. Errors in calculation**

2.22 In addition to the above errors, it is submitted that the NPPA has also erred by taking into account the PTR of Tetanus Toxoid TF brand sold by company. As per the Calculation Sheet the SKU-wise MAT of this brand is only 0.10%. Hence it ought to have been excluded from the calculation. However, the NPPA has included the same resulting in a lower average and therefore lower ceiling price.

2.23 Without prejudice to the submission made above, the correct ceiling price calculations for 0.5 ml and 5 ml packs would be as shown below:

**A. 0.5 ml ampoules**

<b>SKU WISE MAT(Rs.)</b>	<b>PRICE PER UNIT (Rs.)</b>	<b>PRICE THAT OUGHT TO HAVE BEEN CONSIDERED</b>	<b>PRICE PER UNIT CONSIDERED BY THE NPPA IN THE IMPUGNED NOTIFICATION</b>
<b>2.05%</b>	<b>9.07</b>	9.07	4.9
<b>87.89%</b>	<b>8.23</b>	8.23	4.9
<b>1.09%</b>	<b>6.74</b>	6.74	4.9
<b>1.12%</b>	<b>9.22</b>	9.22	4.9
<b>5.42%</b>	<b>9.22</b>	9.22	4.9
0.31%	9.68	-	-
0.31%	8.93	-	-
<b>1.78%</b>	<b>9.68</b>	9.68	4.9
0.03%	9.59	-	-

<b>Sum of PTR per Unit considered</b>	52.16	29.4
<b>Average PTR (6 packs)</b>	8.69	4.90
<b>Add: 16% retail margin</b>	1.39	0.78
<b>Ceiling price</b>	10.08	5.68
<b>WPI reduction 01.04.2016:- 2.7105%</b>	-0.27	-0.15
<b>Final Ceiling price (without local taxes)</b>	9.81	5.53

B. 5 ml ampoules

<b>SKU WISE MAT(Rs.)</b>	<b>PRICE PER UNIT (Rs.)</b>	<b>PRICE THAT OUGHT TO HAVE BEEN CONSIDERED</b>	<b>PRICE PER UNIT CONSIDERED BY THE NPPA IN THE IMPUGNED NOTIFICATION</b>
<b>93.70%</b>	<b>22.06</b>	22.06	22.06
0.19%	19.69	-	-
<b>6.12%</b>	<b>21.84</b>	21.84	21.84
0.10%	21.00	-	21.00
<b>Sum of PTR per Unit considered</b>		43.90	64.90
<b>Average PTR (2 packs)</b>		21.95	-
<b>Average PTR (3 packs as wrongly considered by NPPA)</b>		-	21.63
<b>Add: 16% retail margin</b>		3.51	3.46
<b>Ceiling price</b>		25.46	25.09
<b>WPI reduction 01.04.2016: -2.7105%</b>		-0.69	-0.68
<b>Final Ceiling price (without local</b>		<b>24.77</b>	<b>24.41</b>

2.24 It is pertinent to state that it is economically unviable to follow the ceiling price set by the NPPA by way of the Impugned Notification and if the manufacturers are constrained to follow the existing ceiling price, it would be only a matter of time that such manufacturers will have to stop manufacturing the said vaccine due to losses being incurred by them.

2.25 Thus in view of the same above, Company requested this Department to instruct the NPPA to review the Impugned Notification and appropriately compute the ceiling prices of the 0.5 ml and 5.0 ml packs.

3. Comments of NPPA:

Ceiling price of Tetanus Toxoid Vaccine (Injection) was notified as Rs.5.53/pack (0.5ml) and Rs. 24.41/pack (5ml) vide S.O. 248(E) dated 24.01.2017 and revised to Rs. 5.64/pack (0.5ml) and Rs. 24.89/pack (5ml) vide S.O. 1039(E) dated 01.04.2017 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 **Tetanus Toxoid Vaccine (Injection)**. 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:-

<b>Sl. No.</b>	<b>Company's Grievances</b>	<b>NPPA's comments</b>
1 to	Company has stated that NPPA notified	NPPA had fixed the ceiling price of

3	ceiling price Rs.10.29/pack for Tetanus Toxoid Vaccine (Injection) vide S.O. no. 1673(E) dated 14.06.2013. All the manufacturers of Tetanus Toxoid including Serum Institute of India Pvt. Ltd. implemented the ceiling price of Rs.10.29 for 0.5ml ampoule. Company has stated that all manufacturers in India manufacture and sale only 0.5ml ampoule and 5ml vials. No manufacturer in India manufactures or sells a 1ml vial of Tetanus Toxoid. An ampoule is a single dose pack sold to consumers directly from retail chemists while a 5 ml vial is a multi-dose pack sold mostly to large institutions such as hospitals. NPPA issued corrigendum and modified the meaning of 'each pack' to 1ml.	Tetanus Toxoid vaccine vide S.O. 1673(E) dated 14.06.2013. A corrigendum on the matter was also issued vide S.O. no. 431(E) on 17.02.2014. Calculation sheet of the price notification was put on website on NPPA immediately after fixation of ceiling price on 14.06.2014.
4	The industry made a collective representation to NPPA in 2014. No response was received from NPPA. The basic error in the calculation were:- i. Clubbing of the price to retailer (PTR) 0.5ml ampoules with PTRs of 5ml vial and ii. Calculation of ceiling price of 1ml pack and applying a pro-rata price for 0.5ml ampoule.	NPPA has fixed the ceiling price Rs. 10.29/pack vide S.O. 1673(E) dated 14.6.2013 in accordance with the provisions of DPCO 2013 and the policy adopted by the Authority.
5	Biological E Ltd. filed a review petition in Hon'ble Delhi High Court and Court was pleased to stay the operation against SO 1673(E) dated 14.06.2013 and the corrigendum.	Matter is subjudice.
6	Company has also pointed out that NPPA does not have the jurisdiction to fix the ceiling price of Tetanus Toxoid Vaccine in the light of para 4 of DPCO, 2013 which empower NPPA to fix a ceiling price only for scheduled formulation of specified strength and dosage as specified under the 1 <sup>st</sup> schedule of DPCO, 2013.	NPPA has fixed/revised the ceiling price of Tetanus Toxoid Vaccine considering para 4 of DPCO 2013 and the policy adopted by the Authority.
7	NPPA revised the ceiling price of Tetanus Toxoid at Rs.10.94/ml based on the wholesale price index as per para 16 of DPCO, 2013. Subsequently, on 26.02.2015, the NPPA issued SO 619(E) fixing the ceiling price at Rs.10.36/ml, and vide SO 644(E) dated 02.03.2016, the price was fixed at Rs.11.05/ml. These notifications were pursuant to the annual revision based on the Wholesale Price	NPPA revised the ceiling price of Tetanus Toxoid Vaccine at Rs. 10.94/pack vide S.O. 1156(E) dated 28.4.2014 as per para 16 of DPCO 2013. In the same line NPPA has revised the ceiling price of subject formulation vide S.O. 619(E) and 644(E) dated 26.02.2015 & 02.3.2016 respectively.

	Index (WPI) as per the provisions of para 16 of DPCO involve a fresh calculation of the ceiling price.	
8	On 12.08.2016, NPPA issued a draft version of proposed calculation sheet for revising /notifying the ceiling price/ retail price of Tetanus Toxoid 0.5ml and 5ml. Company vide letter dated 19.08.2016, company highlighted that proposed price calculation for revision/ modification of the ceiling price of Tetanus Toxoid is not as per the provisions of DPCO, 2013.	The Authority examined the representation submitted by the companies but not considered as data submitted was not in line with OM no. 8(34)/2014/Div.II/NPPA dated 13.07.2016 issued by NPPA to submit the requisite data/ information within 10 working days.
9	On 23.08.2016, company highlighted that proposed price calculation for the revision/notification of the ceiling price of Tetanus Toxoid is not as per the stipulated procedure under DPCO, 2013 as:- (a) PTR of all players having over 1% market share had not been considered. (b) The ceiling price has been compared with derived PTR which was worked out on pro-rata basis.	NPPA has fixed the ceiling price as per the data provided by AIOCD-AWACS for the month of August 2015.
10 to 11	Company has requested separate ceiling price for single and multi-dose pack in the light of para 11(3) of the DPCO, 2013.	Based on companies representation, matter was placed before Committee of Expert constituted under para 11(3&4) of DPCO, 2013 and separate ceiling price for Tetanus Toxoid vaccine was fixed vide SO 248(E) dated 24.01.2017 as per the provisions of DPCO, 2013.
12	A committee of experts was formed by DOP as per the provisions of para 11(4) of DPCO to address the issue regarding single and multi dose usage based on therapeutic rationale. On 18.12.2016, Committee of experts recommended for fixation of separate price under para 11(3&4) of DPCO, 2013 for single and multi dose formulation.	Based on companies representation, matter was placed before Committee of Expert constituted under para 11(3&4) of DPCO, 2013 and separate ceiling price for Tetanus Toxoid vaccine was fixed vide SO 248(E) dated 24.01.2017 as per the provisions of DPCO, 2013.
13	Vide letter dated 09.12.2016 and 28.12.2016, company highlighted certain anomalies in the working of the ceiling price of Tetanus Toxoid.	NPPA examined the submission data/information but the same was not found as per OM no. 8(34)/2014/Div.II/NPPA dated 13.07.2016 therefore not considered.
14	Vide letter dated 16.01.2017, NPPA directed the company to submit requisite information which included PTR and Moving Annual Turnover (MAT) data along with supporting documents such as copies of sample invoices to retailers, summary of all invoices issued during the	Documents/ information submitted by company was not as per OM no. 8(34)/2014/Div.II/NPPA dated 13.07.2016 issued by NPPA to submit the requisite data/ information within 10 working days.

	month of August, 2015 and required the said information to be furnished by 23.01.2017.	
15	Company submitted the requisite information/ data vide letter dated 25.01.2017.	Requisite information/data submitted by the company was not as per OM no 8(34)/2014/Div.II/NPPA dated 13.07.2016.
16	Without awaiting the response to its letter dated 16.01.2017, the NPPA on 24.01.2017 issued notification SO 248(E) dated 24.01.2017 fixing the ceiling price of Tetanus Toxoid injection for each pack 0.5ml at Rs. 5.53 and 5.0ml at Rs. 24.41.	NPPA examined the information /data submitted by the company and notified the ceiling price as Rs. 5.53/pack (0.5ml) and Rs. 24.41/pack (5ml) vide S.O. 248(E) dated 24.01.2017 in accordance with the provisions of DPCO, 2013.
17	On 27.01.2017, company issued a letter to NPPA, highlighting the anomalies in the working sheet. The letter was also acknowledged by DOP vide letter dated 07.02.2017.	Documents/ information submitted by company was not as per OM no. 8(34)/2014/Div.II/NPPA dated 13.07.2016 issued by NPPA to submit the requisite data/ information within 10 working days.
18 to 19	As no strength or dosage is fixed for Tetanus Toxoid vaccine, NPPA does not have the jurisdiction to fix the ceiling price of the same in light of the Court order WP(C) 7705 of 2013, judgment dated 10.07.2015.	NPPA has fixed the ceiling price as per the data/ information provided by AIOCD-AWACS for the month of August 2015.
20	NPPA has again committed the error of applying pro-rata pricing while fixing the ceiling price of 0.5ml ampoules of Tetanus Toxoid as Rs.4.90 for 0.5ml ampoules, treating a unit as 1ml rather than 0.5ml.	Issues related to NLEM 2011.
21	Pro-rata pricing is only applicable to tablet and capsule and not to injection.	Matter related to NLEM 2011, therefore, issues raised by company has no merit.
22	No Company in India manufactures or sells a 1ml pack of Tetanus Toxoid Vaccine. Major manufacturers of Tetanus Toxoid vaccines in India are:- 1. Biological E Ltd. (Petitioner No. 1) 2. Serum Institute of India Ltd. (Petitioner No. 2) 3. Dano Vaccines and Biologicals Ltd. (Petitioner No. 3) 4. Indian Immunologicals Ltd. 5. Bio Vaccines Pvt. Ltd. All the manufacturers market and sell both 0.5ml ampoules and 5ml vials of Tetanus Toxoid vaccine. The data of 1 to 3 was not considered while fixing the ceiling price.	NPPA fixed the ceiling price as per the data provided by AIOCD-AWACS for the month of August 2015.
31	Para 9(3) of DPCO mandates that the NPPA take into account the data for the	NPPA has considered the data provided AIOCD-AWACS for the month of



	month of May 2012 when fixing the ceiling price of a scheduled formulation. However, NPPA has taken the data for the month of August 2015.	August, 2015 as per the provisions of DPCO, 2013 and as per the decision taken in 27 <sup>th</sup> Authority Meeting held on 29.03.2016.
32 to 33	NPPA has not taken into account the data as submitted by the petitioner vide letter dated 25.01.2017 while fixing the ceiling price for subject formulation.	NPPA has not taken into account as submitted by the petitioner as it was not as per the line of OM issued by NPPA on 13.07.2016.
34	NPPA has followed an arbitrary and unjustifiable process in gathering the relevant data.	NPPA considered the data provided by AIOCD-AWACS for the month of August 2015.
35 to 36	NPPA has considered the data of Tetanus Toxoid TF 5ml of M/s Serum Institute of India Pvt. Ltd. whose market share is less than 1%.	
37	It is submitted that since the matter is subjudice before the Hon'ble Court the petitioner have not implemented any price changes to the 0.5ml ampoule or 5ml vials since 2014.	
38 to 39	Ceiling price set by NPPA made the products economically unviable to follow the ceiling price.	Most of the companies have followed the ceiling price.

#### **4. Examination:**

4.1 NPPA notified the ceiling price of **Tetanus Toxoid injection at Rs.10.29/pack** vide SO 1673(E), dated 14.06.2013. Subsequently, NPPA issued Corrigendum SO 431(E), dated 17.2.2014 modifying the meaning of 'each pack' in notification to read as '1 ml', which resulted the pro-rata rate of 0.5ml pack as Rs.5.15. Against this, the industry, including the petitioner company, made a collective representation to NPPA on 28.2.2014, highlighting the error of clubbing of PTR of 0.5ml ampoules with PTRs of 5ml vials and calculation of a ceiling price of 1ml pack and applying a pro-rata price for 0.5ml ampoules.

4.2 The drug Tetanus Toxoid was listed at Section 19.3.2 in Schedule I of NLEM 2011 and at Section 22.3.1.8 in Schedule I of NLEM 2015. The dosage form and strength is not mentioned in Schedule I of NLEM 2011 as well as in NLEM 2015.

4.3 NPPA notified the ceiling price of **Tetanus Toxoid injection at Rs.10.29/pack** vide SO 1673(E), dated 14.06.2013. On perusal of the calculation sheet, it is observed that for fixing the ceiling price of the formulation, NPPA considered the PTR of 0.5ml dosage and proportionately arrived at the PTR for 1ml dose. On that basis, the ceiling price of the formulation was fixed at Rs.10.29 per ml dose. However, inadvertently, while notifying the ceiling price, NPPA mentioned it as "Rs.10.29/pack" in the notification SO 1673(E), dated 14.06.2013. Industry implemented the ceiling price of Rs.10.29 per pack of 0.5ml, on the ground that Tetanus Toxoid Injection is manufactured only in the pack size of ampoule of 0.5ml. Later on, NPPA took a corrective measure and issued a corrigendum vide SO 431(E), dated 17.2.2014 clarifying that "Each Pack" be read as "1 ml". Accordingly, the ceiling price of the formulation reduced to Rs.5.15 for a pack of 0.5ml on pro-rata basis.

4.4 The company, in its review application, stated that industry, including the petitioner company, made a collective representation to NPPA in 2014 against the corrigendum issued by

NPPA. On receiving no response from NPPA, one of the manufacturing companies, i.e. Biological E. Limited filed a writ petition in Hon'ble High Court of Delhi and got a stay order dated 27.3.2015 on SO 1673(E), dated 14.06.2013 and Corrigendum SO 431(E), dated 17.2.2014, which is still in force. The writ petition is still pending in Delhi High Court.

4.5 Based on companies representation, NPPA placed the matter before the Expert Committee constituted under para 11(3&4) of DPCO, 2013 on the issue of separate pricing for 0.5ml ampoule and 5ml vial pack. Based on recommendation of Expert Committee, NPPA fixed separate ceiling prices for consumer pack of 0.5ml and hospital pack of 5ml. vide SO 248(E), dated 24.1.2017. However, NPPA restricted the "Price per unit considered" to Rs.4.90, based on ceiling price fixed vide SO 619(E), dated 26.2.2015.

4.6 The ceiling price of Tetanus Toxoid Vaccine fixed by NPPA vide SO 1673(E) dated 14.06.2013 and corrigendum SO 431(E), dated 17.2.2014 were challenged by M/s Biological E.Limited in Hon'ble High Court of Delhi. On the basis of writ petition, the Hon'ble Court has put a stay, vide order dated 27.3.2015 on SO 1673(E), dated 14.06.2013 and corrigendum issued vide SO 431(E), dated 17.2.2014, which is still in force. The writ petition is still pending in Delhi High Court. Since the Hon'ble High Court of Delhi has put a stay on the price ceiling fixed by NPPA, the Corrigendum SO 431(E), dated 17.2.2014 is no longer operable.

4.7 Based on the recommendations of Expert Committee, NPPA fixed separate ceiling prices for 0.5ml ampoules and 5ml. voiles vide SO 248(E), dated 24.1.2017 by restricting the "Price per unit considered" to Rs.4.90 per ml. In spite of the 'stay order' issued by Hon'ble High Court of Delhi on the price fixation order of Tetanus Toxoid Injection in 2014 (and therefore an inoperable order), the price fixation in 2017 by restricting the "Price per unit considered" to Rs.4.90, is not in order.

4.8 The petitioner company also raised the issue of PTR of all players having over 1% market share not being considered by NPPA while calculating the ceiling price of Tetanus Toxoid Injection. Company claimed that while calculating the ceiling price of 0.5ml ampoules, the NPPA has not taken into account the data of M/s Dano Vaccines and Biologicals Pvt. Ltd. and M/s Bio Vaccines Pvt. Ltd. Similarly, in the case of 5ml vials, the data of M/s Dano Vaccines and Biologicals Pvt. Ltd., M/s Indian Immunologicals Ltd. and M/s Bio Vaccines Pvt. Ltd. have not been considered.

4.9 In view of foregoing paras, since Hon'ble High Court of Delhi has issued Stay Order on ceiling price fixed by NPPA in 2014, NPPA needs to be directed to fix the ceiling prices of Tetanus Toxoid Injections, de novo, separately for 0.5 ml ampoules and 5ml voils by considering market price of May, 2012 of those companies having market share of more than 1% of the moving annual turnover.

4.10 On the same issue, M/s Biological E. Limited, M/s Serum Institute of India Limited and M/s Dano Vaccines and Biologicals Pvt. Ltd. have filed separate joint review application, dated 23.2.2017. With this order, the joint review application also stands disposed of.

## 5. **Order:**

**"Hon'ble High Court of Delhi has issued Stay Order on ceiling price fixed for Tetanus Toxoid Vaccine (Injection) by NPPA in 2014. Therefore, on the basis of recommendation of Expert Committee, NPPA is directed to fix the ceiling prices of Tetanus Toxoid Vaccine (Injections), de novo, separately for 0.5 ml ampoules and 5ml voils by considering market price of May, 2012/September, 2013, as the case may be, of those**

**companies having market share of more than 1% of the moving annual turnover, within a period of thirty days of the issue of this order.”**

**“On the same issue, M/s Biological E. Limited, M/s Serum Institute of India Limited and M/s Dano Vaccines and Biologicals Pvt. Ltd. have also filed separate joint review application, dated 23.2.2017. With this order, the joint review application of the above companies also stands disposed of.”**

Issued on this date, the 8<sup>th</sup> day of June, 2018.

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

Copy to :-

1. M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune-411 028.
2. M/s Biological E.Limited and M/s Dano Vaccines and Biologicals Pvt. Ltd., 18/1&3, Azamabad, Hyderabad-500 020.
3. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
4. PS to Hon’ble Minister (C&F), Shastri Bhawan, New Delhi for information.
5. PS to MoS (C&F), Shastri Bhawan, New Delhi for information.
6. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department’s Website