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Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

New Delhi, the 13th November, 2018

S.O. Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide the Resolution of the Government of India in the Ministry of Chemicals and Fertilizers No. 33/7/97-PI.I dated 29th August, 1997 inter alia, to fix prices and notify the changes therein, if any, of bulk drug and formulations, monitor the prices of decontrolled drugs and formulations and oversee the implementation of the provisions of the Drugs (Price Control) Order (DPCO).

2. And whereas the aim of the DPCO is to ensure that essential drugs are available to all at affordable prices, and the Hon'ble Supreme Court of India vide their Order dated 12.11.2002 in SLP No. 3668/2003 (Union of India Vs K.S. Gopinath & others) have directed the Government to ensure that essential and life saving drugs do not fall out of the price control, which has the force of law.

3. And whereas the Ministry of Chemicals and Fertilizers vide S.O.1394(E) dated the 30th May, 2013, in exercise of the powers conferred by Section 3 and 5 of Essential Commodities Act, 1955 has delegated the powers to be exercised by the NPPA on behalf of the Central Government.

4. And Whereas Tetanus Toxoid was included in the Schedule I of the Drug (Prices Control) Order 2013 (DPCO 2013) pursuant to adoption of National List of Essential Medicines 2011 as Schedule I of DPCO 2013 for the purpose of fixation of the ceiling prices of DPCO 2013.

5. And Whereas the para 11(1) of the DPCO 2013 states as follows:

" (1) The average price to retailer calculated as per the provisions in paragraphs 4, 5 and 6 shall be on the dosage basis, (per tablet, per capsule or injection in volume as listed in first schedule) and the ceiling price or retail price of a pack shall be reached by multiplying the same with the number or quantity in the pack as the case may be.

(2) In the event of the unit of the dosage for a scheduled formulation not available in the first schedule, the lowest pack size for that category of medicine, as specified in the Drugs and

Cosmetics Act, 1940 (23 of 1940) and the rules there-under, shall be taken as unit dosage for calculating the ceiling price or retail price as the case may be, for that scheduled formulation and this shall be applicable while calculating the per unit price of even non-scheduled medicines for arriving at the retail price in case of paragraph 5.”

6. And Whereas the para 4 of DPCO 2013 states as follows:

“4. Calculation of ceiling price of a scheduled formulation.–

(1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:

Step1. *First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:*

Average Price to Retailer, P(s) = *(Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)*

Step2. *Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below:*

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above.

M = % Margin to retailer and its value =16

(2) The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also.”

7. And Whereas NPPA works out the ceiling price of the Tetanus Toxid considering the per ml prices of 5ml pack and 0.5ml. The relevant extracts of the working sheet are as follows:

Sl No	Manufacturer Name	Brand Name	Pack size	Price to Retail (PTR) per pack	Price to Retailer (PTR) per ml
1	BIOLOGICAL E	BETT	0.5ML	8.34	16.68
2	BIOLOGICAL E	BETT	5ML	14.96	2.99
3	SERUM INSTITUTE	TETANUS TOXOID	0.5ML	8.34	16.68
4	SERUM INSTITUTE	TETANUS TOXOID	5ML	18.01	3.60
5	SERUM INSTITUTE	TETAVAC	0.5ML	5.46	10.92

6	SERUM INSTITUTE	TETAVAC	5ML	11.72	2.34
		Average PTR per ml			8.87
		Add 16% Retailer Margin			1.42
		Worked out Ceiling Price (per ml)			10.29

Consequently, the ceiling price for the 0.5ml comes to Rs. 5.145 for 0.5ml pack (Rs. 10.29*.5) as per para 11(1), which states " the ceiling price or retail price of a pack shall be reached by multiplying the same with the number or quantity in the pack as the case may be."

8. And Whereas as per para 4 of DPCO 2013, NPPA had fixed the ceiling prices of Tetanus Toxoid under DPCO 2013 in the authority meeting dated 14.6.2013 as Rs. 10.29. However, inadvertently, the ceiling price was notified as Rs. 10.29/pack instead of 10.29/ml vide SO 1673(E) dated 14.6.2013.

9. And Whereas NPPA issued the corrigendum vide SO 431(E) dated 17.2.2014 rectifying its inadvertent mistake and to read 'per pack' as 'per ml'.

10. And Whereas M/s Biological approaches the Hon'ble High court of Delhi against the Notification dated 14.6.2013 read corrigendum dated 17.2.2014 and Petitioner states *"It is the petitioners contention that the earlier notification dated 14.06.2013 was amended by way of a corrigendum dated 17.02.2014 where each pack was defined to mean 1 ml. It is the petitioners Case that, each pack could only mean 0.5 ml as the said quantity conforms to the industry norm."*

11. And Whereas it is noted that while computing the ceiling price, the 'Price to Retailer' (PTR) of 0.5ml has been doubled to reach at per ml price to retailer and the 'Price to Retailer' of 5 ml has been divided by 5 to reach at per ml price to retailer.

12. And Whereas Hon'ble High Court of Delhi, vide its order dated 8.1.2015 in WP 9308/2014 stating that petitioner will be free to take a recourse to a remedy of review, if they so desire.

13. And Whereas M/s Biological filed the review application representing the case to Department of Pharmaceuticals (DoP) which is the authority to review the case under para 31 of the DPC O 2013.

14. And Whereas, DoP vide its order dated 4.3.2015, rejected the contention of the Applicant M/s Biological (E) Ltd passed the order "The points raised by the petitioner have no merit and, therefore, the review application is rejected." stating the following :

"i) The first point raised by the petitioner is that the ceiling price has to be fixed for 0.5 ml ampoule and cannot be fixed for 1 ml. as there is no manufacturer that sells 1 ml pack for Tetanus Toxoid vaccine in the market. The petitioner in support of its argument has referred to Rule 105, rule 122 (E) and Schedule P.1 of the Drugs and Cosmetics Rule, 1945. The petitioner has also referred to the drug license given to them which stipulates that lowest pack size is 0.5 ml ampoule.

In this connection it may be mentioned that para 4(1) of DPCO 2013 clearly stipulates that sum of the prices to retailer of all brands and generic versions of the medicines having market share more than or equal to 1% has to be considered while arriving at the average price to retailer and the ceiling price. It does not stipulate that the price of an ampoule of the lowest volume will only be considered. Therefore, as per para 4(1) of DPCO 2013 all brands and generic versions irrespective of the size have to be considered by NPPA. The calculation sheet as uploaded on the website of NPPA shows that though Tetanus Toxoid injection of 1 ml ampoule is also available in the market its MAT value and the percentage share was very low. NPPA has, therefore, considered 0.5 ml pack and 5 ml packs which were available in the market.

Further para 11(1) states that average price to retailer shall be calculated as per provisions of para 4,5 & 6 and the ceiling price or retail price of a pack shall be reached by multiplying the same with the number or quantity in the pack. If the petitioner is manufacturing a formulation with less than 1 ml i.e. 0.5 ml they could reach pack price by multiplying 1 ml price with $\frac{1}{2}$. DPCO 2013 does not anywhere states that larger packs will be excluded. Even Tetanus Toxoid Vaccine at sl. No.11 of the license issued to the petitioner clearly shows single dose vial - 0.5 ml and 10 dose vial - 5 ml. While arriving at the ceiling price NPPA has taken the data pertaining to both the packs . Thus the point raised by the petitioner has no merit.

(ii) The second point raised by the petitioner is that NPPA has not fixed the ceiling price of 0.5 ml ampoule within the provision of DPCO 2013. Thus the provisions of para 31 are not applicable.

As mentioned above in reply to point No. (i) the ceiling price issued by NPPA has to be multiplied with the quantity in the pack size for arriving at the ceiling price of the pack. DPCO 2013 does not anywhere state that the larger pack should be excluded for arriving at the ceiling price or retail price.

(iii) Third point raised by the petitioner is that DPCO 2013 is based on the principle of market based pricing. NPPA is required to determine the ceiling price specifically for the available

pack sizes in the market. The petitioner submitted that IMS data suffers from severe infirmities and does not adequately reflect the pricing of their formulation.

DPCO 2013 has nowhere excluded larger pack sizes as already mentioned in reply to point (i). All brands or generic versions of the medicines have to be taken into account. If companies are giving discounted pricing for the larger packs to the doctors, etc. there is no reason why the benefit of discounted prices should not be made available to the patients. A perusal of the cost sheet shows that there is more than 50% variation in prices within the same size of formulation. The DPCO, 2013 by clubbing all packs and sizes seeks to rationalize the prices and the petitioner has no merit in this point.

(iv) The fourth point raised by the petitioner is that clubbing 0.5 ml ampoule and 5 ml vial for calculating the ceiling price would lead to impracticable implications on the manufacturing cost.

This point has already been discussed above as the DPCO 2013 provides in para 4(1) to include all brands and generic versions irrespective of their size or volume. Under para 11 the prices of the pack have to be calculated by multiplying the ceiling price with the volume. There does not seem to be any practical difficulty in calculating the price of 0.5 ml. In regard to the point raised by the petitioner about the implication on manufacturing cost it is mentioned that DPCO 2013 is based on market prices and not on cost basis."

15. And Whereas Hon'ble High court of Delhi in its order dated 27.3.2015 in WP 3126/2015 stayed the notification dated 14.6.2013 read with corrigendum dated 17.2.2014.

16. And Whereas the Schedule I of the DPCO 2013 was revised with effect from 10.3.2016 pursuant to revision of National list of Essential Medicines. Tetanus Toxoid was again included in the Schedule I of the DPCO 2013 vide SO 701(E) notification dated 10.3.2016

17. And Whereas as per para 18 of the DPCO 2013, "The revision of ceiling prices on the basis of moving annual turnover value shall be carried out,-

(i) as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier."

18. And Whereas the para 11 of the DPCO 2013 was amended vide SO 1192(E) dated 22.3.2016 by inserting the following para 11(3) and 11(4)

“(3) Notwithstanding anything contained in sub-paragraph (1) and (2), in the case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I of the Drugs (Prices Control) Order, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specified therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made there under for the same formulation.

(4) The Government shall form a Committee of Experts, as it may deem fit, within a period of fifteen days from the date of issue of this order, to recommend fixing of separate ceiling price of scheduled formulations or retail price of a new drug as per the above parameter.”

19. And Whereas pursuant to amendment in the para 11 of the DPCO 2013, NPPA has the power to fix the separate ceiling prices for different pack-size based on recommendation of the expert Committee. Accordingly, NPPA has considered the various representations and the fixed the separate ceiling price for different packs of various formulations. Such ceiling prices are applicable prospectively.

20. And Whereas NPPA computed the ceiling price of Tetanus Toxoid for 0.5ml and 5ml separately considering the data for Aug 2015 as per para 9(5) of the DPCO 2013 restricting the Price to Retailer (PTR) on the basis of existing ceiling price. As per prevalent practice NPPA has placed the draft working sheet on the website of NPPA vide OM no 8(34)/2016/DP/(NPPA)-Div II dated 12.8.2016.

21. And Whereas M/s Biological E Ltd and M/s Serum Institute gave a representation on the draft working of the ceiling prices mainly objecting that the Price to Retailer should not have been restricted based on the prevalent ceiling price.

22. And Whereas NPPA after examination of the representation , rejected the contention of the applicant and notified the ceiling prices as Rs. 5.53 for 0.5ml and Rs. 24.41 for 5 ml pack of Tetanus Toxoid vide SO 248(E) dated 24.1.2017.

23. And Whereas M/s Serum Institute of India Ltd. filed a review application under para 31 of the DPCO 2013 vide its letter dated 22.2.2017. On the same contention, a joint review

application by other manufacturers including Serum Institute of India Ltd, M/s Biological (E) Ltd etc was also filed with DoP on 23.2.2017.

24. And Whereas after examining the matter, the Department of Pharmaceuticals (DoP) in its order no 31015/27/2017-Pricing dated 8.6.2018 directed the following:

“ 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.”

25. Now, In implementation of directions given in line with the review orders issued by the Department of Pharmaceuticals (DOP) vide order(s) specified in column (6) of the table herein below passed by the Department of Pharmaceuticals under para 31 of Drugs (Prices Control) Order, 2013 and in exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) specified in the Column (7) of the table regarding formulation specified in mentioned in the table in so far as it relates to formulation pack mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby fixes/ revises the price as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulation(s) specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)	Review Order number and date	Existing SO number and date
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.	Tetanus Toxid	Injection	Each Pack (0.5ml)	9.95	31015/27/2017-Pricing dated 8.6.2018	1461(E) dated 2.04.2018 (at Sl. No. 788)
2.	Tetanus Toxid	Injection	Each Pack (5ml)	21.43	31015/27/2017-Pricing dated 8.6.2018	1461(E) dated 2.04.2018 (at Sl. No. 789)

Note:

- (a) All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and

- services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.
- (b) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.
 - (c) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.
 - (d) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form-V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.
 - (e) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.
 - (f) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.
 - (g) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.
 - (h) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.
 - (i) For any other pack size manufactured, the manufacturer shall approach NPPA for specific price approval for its formulations along with the relevant market data duly authenticated for fixation of the ceiling price.
 - (j) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

PN/192/60/2018/F

F. No. 8(60)/2018/D.P./NPPA-Div.-II

(BALJIT SINGH)
Assistant Director

