(2019) 02 DEL CK 0249

In the Delhi High Court

Case No : Civil Writ Petition No. 3126 Of 2015, Civil Miscellaneous No. 5576 Of 2015, 27446 Of 2018

M/S. Bilogical E Ltd. & Anr — APPELLANT

Vs

National Pharmaceutical Pricing Authority & Ors — RESPONDENT

Date of Decision : 19-02-2019

Acts Referred:
Essential Commodities Act, 1995 — Section 3

Citation : (2019) 02 DEL CK 0249

Hon'ble Judges : Vibhu Bakhru, J

Bench : Single Bench

Advocate : Abdullah Hussain, Kanika Nayar, Arjun Nihal Singh, Prerna Parashar, Anurag Ahluwalia, Sumit Rajput, Aditya Sengar

Final Decision : Disposed Off

Judgement

Vibhu Bakhru, J

1. Petitioner no.1 (Biological E Ltd. - hereafter "the petitioner") is a company, inter alia, engaged in the manufacture and supply of vaccines, which includes a Tetanus Toxoid vaccine. The petitioner has filed the present petition, inter alia, impugning an order dated 14.06.2013 (S.O.No.1673(E) - hereafter "the impugned notification") passed by the National Pharmaceutical Pricing Authority (hereafter "NPPA"), read with a corrigendum (S.O. No.431(E)) dated 17.01.2014 (hereafter "the impugned corrigendum"). By the impugned notification, NPPA had fixed the ceiling price for Tetanus Toxoid Injection at Rs. 10.29 for "each pack". The petitioner is not aggrieved by the said notification, inasmuch as, it interpreted "each pack" to mean an ampoule of 0.5ml. The petitioner is, essentially, aggrieved by the impugned corrigendum wherein the term "each pack" has been corrected to read as "1 ml". Consequently, by the impugned notification, the ceiling price for 1 ampoule of 0.5ml of Tetanus Toxoid Injection stands fixed at `5.145 (`10.29 X 0.5).

2. The petitioner also impugns a show cause notice (F. no. 25{332)2014/Div. IV(OC-II)/NPP) dated 20.10.2014 (hereafter "impugned show cause notice"), whereby the petitioner has been called upon to show cause as to why action should not be taken against it for recovering an amount of Rs. 27,38,33,752/-, alongwith appropriate interest, being the amount allegedly overcharged by the petitioner for the sale of the Tetanus Toxoid vaccine. The impugned show cause notice was followed by a demand notice (F.No.25(332)2014/Div.IV(OC-II)/NPPA) dated 28.11.2014 (hereafter "impugned demand notice"), calling upon the petitioner to deposit a sum of `33,28,03,171/- as the amount overcharged from consumers and interest thereon.

3. The petitioner had filed a review under paragraph 31 of the Drugs (Prices Control) Order, 2013, (hereafter "DPCO, 2013") seeking review of the impugned notification. The said review petition was dismissed by the Department of Pharmaceuticals, Government of India (respondent no.3) by an order (No. 31015/68/2014-PI.I) dated 04.03.2015 (hereafter "impugned review order"). The petitioner has also assailed the impugned review order in this petition.

4. Admittedly, the recommended dose for the Tetanus Toxoid vaccine is 0.5ml and the petitioner and other manufacturers manufacture and sell Tetanus Toxoid in ampoules of 0.5ml. In addition, vials of 5ml are also sold to bulk purchasers (such as hospitals and the armed forces). The pricing of the 0.5 ml ampoule and 5 ml pack are materially different and there is no linear correlation. The data collected by the NPPA at the material time indicated that the price of 0.5 ml ampoules ranged from Rs. 5.46 to Rs. 8.34 and the price for vials of 5ml ranged from Rs. 11.72 to Rs. 18.01. The obvious difference in the price is also related to the packaging of the said vaccine. Essentially, the grievance of the petitioner is that the NPPA has fixed the ceiling price for the vaccine in question by computing the average price of ampoules of .05 ml and vials of 5 ml. This, according to the petitioner, has led to anomalous result where the ceiling price of the vaccination is unviable. This is so, because per ml price to retailer (PTR), the Tetanus Toxoid vaccination sold in vials of 5 ml each ranges from Rs. 2.34 to Rs. 3.60, whereas the price (that is, by multiplying the price of an ampoule by 2), ranges from Rs. 10.92 to Rs. 16.68 per ml. According to the NPPA, the ceiling price is required to be fixed under the DPCO, 2013 by considering all pack sizes and, therefore, the impugned notification fixing the ceiling price cannot be faulted.

5. Subsequent to the filing of the present petition, respondent no.2 has accepted the stand of the petitioner and other manufacturers and the NPPA has, by a notification (S.O. No.5727 (E)) dated 12.11.2018, fixed two separate ceiling prices - one for the Tetanus Toxoid Injection for the 0.5ml pack and one for the Tetanus Toxoid Injection vial for the 5ml pack. However, the respondents contend that the two separate ceiling prices fixed as per notification dated 12.11.2018 - even though fixed on basis of the market price data pertaining to the period September 2012/July 2013 - cannot be applied retrospectively. This contention is founded on the assumption that prior to insertion of Sub-paragraph (3) and (4)

to Paragraph 11 (which were inserted by S.O.1192(E) dated 22.03.2016), the DPCO, 2013, did not permit fixing of separate ceiling price for the same formulation.

Factual Background

6. The petitioner was granted a license for the manufacture and sale of Tetanus Toxoid by the Drugs Controller General of India (Respondent No. 4 - DGCI), by a License Certificate dated 06.09.2012. The said license was valid till 31.12.2016 and the lowest pack size/single dose vaccine for Tetanus Toxoid was fixed as a 0.5 ml ampoule.

7. The NPPA issued the impugned notification in exercise of the powers conferred by Paragraph 4, 11 and 14 of the Drugs (Prices Control) Order, 2013 (DPCO, 2013), whereby the ceiling price of Tetanus Toxoid Injection was fixed at Rs. 10.29 for "each pack". The said notification did not indicate the quantity of the formulation in "each pack".

8. The NPPA, vide the impugned corrigendum order, amended the impugned notification to provide that the term "each pack", as stated in the impugned notification, be read as "1 ml".

9. Prior to the issuance of the impugned corrigendum, the petitioner and other manufacturers had interpreted "each pack" to be read as 0.5 ml, which was in line with the industry practice. On 28.02.2014, the petitioner and other manufacturers of Tetanus Toxoid, being aggrieved by the Corrigendum, made a representation to the Chairman of the NPPA. The said representation also contained a rate sheet on which the calculation of the ceiling price appeared to be based. The petitioner contends that the NPPA relied upon market data as collected by IMS Health, a pharmaceuticals market data specializing company (hereafter "the IMS Data"),which was fraught with several errors and inconsistencies.

10. The NPPA, vide a letter dated 12.06.2014, alleged that the petitioner was overcharging for the product - that is, the 0.5 ml ampoule of "Bett Tetanus" - by selling the same at Rs. 11.61 per pack even though the NPPA, vide the impugned notification, had set the ceiling price at Rs. 10.29 per pack. The said letter also demanded that the petitioner furnish full details of production and sales of the "Bett Tetanus" 0.5 ml pack/ ampule.

11. The petitioner, vide its reply dated 30.06.2014, sought additional time to furnish the information as demanded by the NPPA. On 28.07.2014, the petitioner submitted its reply furnishing the documents as demanded by the NPPA by its letter dated 12.06.2014.

12. Thereafter, the NPPA issued the impugned show cause notice on 20.10.2014 to the petitioner. By the impugned show cause notice, the petitioner was asked to justify selling "Bett Tetanus Vaccine" at a price higher than the ceiling price as notified by the impugned notification. It was alleged that based on the data

provided by the petitioner vide its letter dated 28.07.2014, it was estimated that the petitioner had charged an amount of Rs. 27,38,33,752/- in excess from the consumers. The petitioner was called upon to show cause within twenty one days from the date of issue of this letter as to why action should not be taken to recover the aforesaid amount

13. The petitioner responded to the impugned show cause notice by a letter dated 29.10.2014, disputing that the NPPA could raise a demand for the period between July, 2012 and September, 2013, as the same was prior to the issuance of the DPCO, 2013. The petitioner states that subsequently, it furnished the information as required by letters dated 26.11.2014 and 26.12.2014.

14. On 16.11.2014, the petitioner and other vaccine manufacturers made another representation to the Minister of Chemical and Fertilizers, Government of India; The Secretary, Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals), Government of India (i.e., the Secretary of respondent no. 2) and; The Chairman of the NPPA.

15. Respondent No. 2 treated the said industry representation as a Review Application filed by the petitioner, and rejected the said Review Application by an order dated 30.01.2015, for not being within the limitation period of 30 days as specified for a Review Application under Paragraph 31 of the DPCO, 2013.

16. A letter from the Director (Cost), NPPA, dated 20.11.2014, was received by the petitioner. The said letter referred to the industry representation dated 28.02.2014, and requisitioned certain information from the petitioner. The petitioner submitted the required information as asked for, vide a letter dated 29.10.2014. The petitioner also duly responded to the NPPA"s letter dated 20.11.2014, vide a letter dated 15.12.2014.

17. On 25.11.2014, the local drug inspector visited the premises of petitioner for verification of the data that had been submitted to the NPPA vide a letter dated 29.10.2014. The said verification confirmed that the petitioner was charging Rs. 10.29 per pack of 0.5 ml Tetanus Toxoid Vaccine.

18. The NPPA issued the impugned demand notice dated 28.11.2014, calling upon the petitioner to deposit Rs. 33,28,03,171/- on account of overcharging its customers and interest at the rate of 15% calculated up to 15.12.2014, within 15 days of issue of the letter.

19. On 01.12.2014, the petitioner made a request to the Chairman of the NPPA for a personal hearing and on 12.12.2014, certain representatives of the petitioner met with the Member Secretary and the Chairman of the NPPA regarding the ceiling price of Tetanus Toxoid.

20. Thereafter, the petitioner preferred a writ petition (M/s Biological E Ltd. and Anr. v. NPPA & Anr: W.P. (C) 9308/2014) before this Court, against the alleged arbitrary determination of ceiling price of Tetanus Toxoid for a one ml pack at Rs. 10.29/-. By an order dated 08.01.2015, passed by the Coordinate Bench of this

Court, the operation of the impugned demand notice dated 28.11.2014 was stayed, subject to part payment of 25% of the payment stipulated in the Demand Notice issued by the NPPA.

21. The petitioner preferred an appeal against the order dated 08.01.2015. The Division Bench of this Court, by its order dated 22.01.2015 (captioned M/s Biological E Ltd. & Anr. v. NPPA and Ors, bearing LPA 31 of 2015), modified the Order dated 08.01.2015, staying the impugned Demand Notice on furnishing of a security for 25% of the impugned demand. The petitioner was further granted liberty to file a review petition in terms of Paragraph 31 of the DPCO.

22. Thereafter, the petitioner furnished the requisite security bond, through a fixed deposit receipt for the specified amount on 05.02.2015. On 30.01.2015, the petitioner filed a Review Application before respondent no.3.

23. By the order dated 04.03.2015, the review petition preferred by the petitioner under Paragraph 31 of DPCO, 2013 was rejected for being without merit.

24. On 05.03.2015, this Court disposed of the Writ Petition (captioned M/s Biological E Limited and Anr. v. National Pharmaceutical Pricing Authority and Ors, bearing W.P. (C) 9308 of 2014) with liberty to the petitioner to file a fresh petition, assailing the impugned Review Order. This Court further directed that the interim relief granted by the Division Bench of this Court would remain valid for four weeks.

25. This Court, vide its order dated 27.03.2015 in the present petition, stayed the impugned review order, the impugned notification read with the impugned corrigendum, the impugned show cause notice and the impugned demand notice in the same terms and conditions as imposed by this Court on 05.03.2015 in W.P. (C) 9308/2014.

26. By a notification (S.O. 701(E)), Schedule-I of the DPCO, 2013 was revised with effect from 10.03.2016 by substituting the National List of Essential Medicines, 2015, in place of the National List of Essential Medicines, 2011. Tetanus Toxoid continued to be listed under Schedule-I of the DPCO.

27. Paragraph 11 of the DPCO, 2013 was amended vide S.O. 1192(E) dated 22.03.2016, by inserting Sub-Paragraphs (3) and (4) to Paragraph 11. Pursuant to the amendment, the NPPA was given power to fix separate ceiling prices for different pack sizes, based on recommendations of the Expert Committee. Accordingly, the NPPA considered the various representations and fixed the separate ceiling price for different packs of various formulations.

28. The NPPA computed the ceiling price of Tetanus Toxoid ampoules of 0.5 ml and 5 ml separately considering the data for August 2015 as per Sub-Paragraph (5) of Paragraph 9 of the DPCO, 2013, restricting the Price to Retailer (PTR) on the basis of the existing ceiling price. As per prevalent practice, the NPPA had placed the draft working sheet on its website (vide OM No. 8 (34)/2016/DP/

(NPPA)-Div II dated 12.08.2016).

29. The petitioner and Serum Institute of India Ltd. (SIIL) gave a representation on the draft working of the ceiling prices, mainly, objecting to the price fixation on the prevalent ceiling price. However, the NPPA rejected the representation, and by a notification (S.O. 248 (E)) dated 24.01.2017, notified the ceiling prices as Rs. 5.53/- for the 0.5 ml ampoule and Rs. 24.41 for the 5 ml pack of Tetanus Toxoid.

30. On 22.02.2017, SIIL filed a review application under paragraph 31 of the DPCO, 2013. In addition, on 23.02.2017, SIIL along with other manufacturers including the petitioners, filed a joint review petition with the Central Government - Department of Pharmaceuticals (DoP).

31. After examining the matter, the DoP by its order dated 08.06.2018 (order No. 31015/27/2017- Pricing), directed NPPA to fix the ceiling prices of Tetanus Toxoid (Injections), de novo, separately for the 0.5 ml ampoules and the 5 ml ampoules by considering the market price as prevailing in May, 2012/ September, 2013. Further, vide the same order, DoP disposed of the joint review applications of the petitioner and SIIL.

32. By the notification S.O. 5727 (E) dated 13.11.2018, the NPPA fixed the ceiling price of Tetanus Toxoid as set out below:-

SI No.

Name of

Dosage

Unit

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Review

Existin

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Form

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Order and

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Scheduled

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Pric

date

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Formation

Strength

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(Rs)

date

(1)

(2)

(3)

(4)

(5)

(6)

(7)

1.

Tetanus

Injection

Each

9.95

31015/27/20

1461(E)

Toxoid

Pack

17- Pricing

dated

(0.5

dated

2.04.2018

ml)

08.06.2018

(at SI. No.

788)

2.

Tetanus

Injection

Each

21.4

31015/27/20

1461(E)

Toxoid

Pack

3

17- Pricing

dated

(5

dated

2.04.2018

ml)

08.06.2018

(at SI. No.

789)

Reasons and Conclusion

33. The DPCO, 2013 has been issued by the Central Government in exercise of powers conferred under Section 3 of the Essential Commodities Act, 1995, and pursuant to the National Pharmaceutical Pricing Policy, 2012 (NPPP-2012). The principal objective of the said policy was to put in place the regulatory framework for pricing drugs so as to ensure availability of required medicines (Essential Medicines) at reasonable prices while providing sufficient opportunity for innovation to support the growth of the industry. One of the key features of price regulation under the NPPP, 2012 is to introduce "market based price". This was materially different from the principles of regulatory pricing under the Drug Policy, 1994, which envisaged regulation of prices on the basis of cost. Under the

said policy, ceiling prices were fixed based on the cost data provided by various manufacturers. The NPPP, 2012 brought about a material shift in the methodology of fixing ceiling price of essential medicines. In terms of NPPP 2012, the ceiling prices would be based on information widely available in the public domain as against costing data as provided by a manufacturer. The said policy provided for fixing of the ceiling prices by adopting the simple average price of all brands having market share more than or equal to one percent of the total market turnover of the said medicine. The relevant extract of NPPP 2012 indicating the manner in which ceiling prices were to be fixed, is set out below:-

"(iv) The methodology of fixing a ceiling price of NLEM medicines, by adopting the Simple Average Price of all the brands having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine, will be as per the formula below:

(Sum of prices of all the brands of the medicine having market share more than and equal to 1% of the total market turnover of that medicine) / (Total number of manufacturers producing such brands of the medicine).

(v) The formulations will be priced only by fixing a Ceiling Price (CP). Manufactures would be free to fix any price for their products equal to or below the CP. The CP"s would be fixed on the dosage basis, such as per tablet/capsule/ standard injection volume as listed in NLEM-2011.

(vi) The Ceiling Price will be fixed on the basis of readily monitorable Market Based Data (MBD). To begin with, the basis for this readily monitorable market data would be the data available with the pharmaceuticals market data specializing company - IMS Health (IMS). Wherever required this data would be checked by appropriate survey/evaluation by the National Pharmaceutical Pricing Authority (NPPA). As the IMS data gives price figures for stockiest level prices hence in order to arrive at ceiling Price (which will be the maximum retail price), the IMS price will be further increased by 16% as margin to the retailer so as to arrive at a reasonable ceiling price chargeable from the consumers."

34. It is apparent from the above that the rationale for fixing a ceiling price is to take the simple average of the prices charged by various manufacturers. Clearly, the said rationale would hold good only if there is homogeneity in the products. In a free competition environment, the simple average of prices charged by various manufacturers would ensure that efficient manufacturers are duly rewarded for their efficiency, and further ensure that the consumers are not mulcted with higher prices on account of profiteering or on account of higher cost due to inefficiency of any particular manufacturer. This rationale would fail if prices of different products are clubbed together to arrive at an average price.

35. DPCO, 2013 embodied the aforesaid principles and provided for the calculation of a ceiling price of a scheduled formulation. Paragraph 4 of the DPCO, 2013, is set out below:-

"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."

36. Paragraph 9 of the DPCO, 2013 provides for calculation of reference data and source of market based data. In terms of paragraph 9(1) of the DPCO, 2013, initially the data available with IMS (Health) is required to be used. Paragraph 11 of the DPCO, 2013 expressly provides that the average price to retailer (PTR) shall be calculated on the dosage basis. Paragraph 11 of the DPCO, 2013, as applicable at the material time, is set out below:-

"11. Ceiling price or retail price of a pack.- (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 thereunder, 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."

37. Paragraph 11 of the DPCO, 2013 was amended by a notification S.O. No. 1192(E)) dated 22.03.2016 by insertion of Sub-paragraphs (3) and (4) to

Paragraph 11, which read as under:

"(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 thereunder 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."

38. As is apparent from the plain language of Sub-paragraph (1) of Paragraph 11 of the DPCO, 2013, the ceiling price calculated under Paragraph 4 was required to be on dosage basis, as specified in Schedule-I to the DPCO, 2013.

39. Although, Tetanus Toxoid is included in Schedule-I (under entry 19.3.2), the strength of the said vaccine was not specified. Schedule-I of the DPCO, 2013 was substituted by NLEM, 2015 by a notification dated 10.03.2016. The amended Schedule also includes the Tetanus Toxoid Injection vaccine under Entry 22.3.1.8. However, the same also does not specify the strength of the Tetanus Toxoid vaccine. In fact, Schedule I - to the DPCO, 2013 does not specify the strength of any of the vaccines for universal immunization.

40. Sub-paragraph(3) of Paragraph 11 of the DPCO, 2013 expressly provides that in cases where the unit of the dosage is not available in the First Schedule, the lowest pack size for that category of medicine, as specified in the Drugs and Cosmetics Act, 1940 and the Rules made thereunder, would be taken as a unit dosage for calculating the ceiling price or the retail price as the case may be. Admittedly, a Tetanus Toxoid Vaccine is available in ampoule of 0.5ml, which is the recommended dose of the said vaccine. Thus, clearly, the ceiling price was required to be fixed for an ampoule of 0.5ml.

41. Although, it is contended on behalf of the respondents that Tetanus Toxoid is also available in 1ml, it is not disputed that the recommended dosage for the said vaccination is 0.5ml. It is also conceded that only a very small fraction of the total quantity of vaccines manufactured is available in pack size of 1ml. In terms of Paragraph 4 of the DPCO, 2013, the NPPA has excluded the price data of such manufacturers (those selling the vaccine in packs of 1 ml), as the turnover of none of such manufacturers constitutes one per cent or more of the total market turnover of the said vaccine. In the aforesaid view, there can hardly by any dispute that NPPA was required to fix the ceiling price for the Tetanus

Toxoid Vaccine in a pack size of 0.5ml. Thus, the impugned notification read with the corrigendum is flawed.

42. It is contended on behalf of the respondents that even if the ceiling price was required to be fixed for a pack size of 0.5ml, the same could easily be derived from the impugned notification by dividing the ceiling price so fixed by two. According to the respondents, the same is permissible in view of Sub-paragraph (1) of Paragraph 11 of the DPCO, 2013, which expressly provides that a retail price for a pack would be reached by multiplying the same with the number or quantity in the pack as the case may be. Since, in the present case, the quantity in the ampoule was half of the quantity as specified in the impugned notification (read with the impugned corrigendum), the said price was required to be multiplied by a factor of 0.5ml.

43. The aforesaid contention is not unsubstantial. Even though, the NPPA was required to fix the ceiling price for the lowest pack size for that category of medicine, there would be no difficulty in ascertaining the ceiling price of the lowest pack size by applying the simple mathematical formula as provided in Sub-paragraph (1) of Paragraph 11 of the DPCO, 2013. But, this is not the principal controversy in the present petition.

44. The essential dispute relates to the manner in which the ceiling price has been computed. The notification dated 13.11.2018 indicates the manner in which the NPPA has computed the ceiling price of the Tetanus Toxoid vaccine. It had considered the prices of the 5ml vials as well as the 0.5ml ampoule to arrive at an average price. Paragraph 7 of the said notification dated 13.11.2018, which indicates the above, is set out below:-

"7. And Whereas NPPA worked 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

Manufacturer

Brand

Pack

Price to

Price to

No.

Name

Name

size

Retail

Retailer

(PTR)

(PTR) per

per pack

ml

1

BIOLOGICAL E

BETT

0.5ML

8.34

16.68

2.

BIOLOGICAL E

BETT

5ML

14.96

2.99

3.

SERUM

TETANUS

0.5ML

8.34

16.68

INSTITUTE

TOXOID

4.

SERUM

TETANUS

5ML

18.01

3.60

INSTITUTE

TOXOID

5.

SERUM

TETAVAC

0.5ML

5.46

10.92

INSTITUTE

6.

SERUM

TETAVAC

5ML

11.72

2.34

INSTITUTE

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."

45. It is apparent from the above that the NPPA had not drawn any distinction between vials of 5ml or the ampoule of 0.5ml, even though the there was a wide variation in the price of vaccines sold in ampoules of 0.05 ml and vials of 5 ml, as is apparent from the price data set out above.

46. It is not disputed that although the formulation is same in both the packs - 0.5 ampoule as well as 5 ml vials - there was material difference in the price, on account of their packaging. It is also not disputed that vials of 5ml are of little use for a retail consumer as a dosage of the said vaccine is 0.5ml. It is also not disputed that there is a separate set of consumers that uses the ampoules of 0.5ml and a separate set of consumers that use vials of 5 ml. Concededly, ampoules of 0.5 ml are used to administer the vaccines to a single person and vials of 5 ml are brought by bulk consumers (such as hospitals and the Armed forces) who are in a position to use large quantities of the vaccines to administer them to multiple persons.

47. The price of 0.5ml ampoule takes into account the cost of packaging, which may not be materially different from the cost of packaging of 5ml vials. Indisputably, there is no linear co-relation, inasmuch as, the cost of a 5 ml vial is not the same as the cost of ten ampoules of 0.5ml each. Plainly, if this distinction is not recognized, the entire rationale of determining prices on a simple average basis would be corrupted. As noticed above, it is implicit in fixing an average price to retailer that the products are homogenous; if data of materially different products are used for arriving at the average price, the results would, obviously, be flawed.

48. The petitioner manufactures ampoules of 0.5 ml, which is the recommended dose of the vaccine. Thus, Tetanus Toxoid is required to be retailed in units of 0.5 ml. The NPPA was, consequently, required to determine the average PTR (price to retailer) of Tetanus Toxoid ampoule of 0.5.ml. In order to maintain the statistical integrity and the efficacy of the methodology, it was essential that only the data relating to similar products was used. The wide variation in the PTR of the vaccines sold in ampoules of 0.5ml and vials of 5 ml is clearly indicative of the fact that the said products could not be clubbed together for the purposes of determination of the average selling price.

49. The aforesaid principle was clearly accepted by respondent no.3 and, accordingly, the review petitions filed by M/s Serum Institute of India limited under Paragraph 31 of the DPCO, 2013 against the price notification dated 24.01.2017, S.O. No.248(E), was allowed by an order dated 08.06.2018, whereby the NPPA was directed "to fix the ceiling price of Tetanus Toxoid Vaccine (Injection) de novo, separately for 0.5ml ampoules and 5ml voiles by considering the market price of May, 2012/September, 2013 as the case may be of those companies having market share of more than one per cent of the moving annual of the turnover within a period of 30 days of the issue of the order." The petitioner herein, M/s Serum Institute of India Pvt. Ltd. and Dano Vaccines and Biologicals Pvt. Ltd. had also filed a review application dated 23.02.2017 against the aforesaid notification which was disposed of in terms of the order dated 08.06.2018.

50. It is apparent from the above that the contention of the petitioner was accepted. Admittedly, the direction issued by respondent no.3 was complied with

and has resulted in the issuance of the notification dated 13.11.2018. In terms of the said notification, the ceiling price for a pack of 5ml of Tetanus Toxoid Injection has been fixed at `9.95 and the price of 0.5ml pack of Tetanus Toxoid Injection has been fixed at ` 21.43.

51. It is important to note that the aforesaid prices have been fixed based on the market prices of the said vaccine as prevailing during May, 2012/September, 2013. Thus, the said prices would also be relevant for fixing the average price at the time of issuance of the impugned notification.

52. Mr Ahluwalia, learned counsel for the respondents had contended that the said notification dated 13.11.2018, fixing the aforesaid ceiling price, applies prospectively. He submitted that separate ceiling price for 0.5ml ampoule and 5ml pack could not be fixed prior to 22.03.2016, as the enabling provisions to do so were introduced by inserting Sub-paragraph (3) and (4) in paragraph 11 of the DPCO, 2013, only with effect from 22.03.2016.

53. The aforesaid contentions are unpersuasive. Even though, express provisions were not included for fixing a separate price for different pack sizes prior to 20.02.2016, however, the NPPA had sufficient discretion to fix a ceiling price by taking into account the relevant data. As discussed above, there was no dispute that the NPPA was required to fix the ceiling price of Tetanus Toxoid Injection in a pack size of 0.5ml. Further, it is also clear that a 0.5ml vial could not be included for determining an average price of the said product. Thus, clearly, the NPPA was not precluded in fixing a ceiling price of 0.5ml based on the average price to retailer of the said ampoules.

54. This Court is of the view that the NPPA was not precluded in fixing a separate price for a 5ml pack as well, if it found that the pricing data for 0.5ml ampoule was not relevant for determining the price for the same.

55. Sub-paragraph (1) of Paragraph 11 of the DPCO, 2013 provides for a mathematical formula for ascertaining the ceiling price of a pack of multiplying the ceiling price of the formulation with the number or quantity of the same in the pack as the case may be. This formula clearly works where the pack includes the formulation in units which are notified in a particular pack size. In the present case, if the 5ml pack consisted of 10 ampoules of 0.5ml, there would be no difficulty in applying the formula as provided under Sub-paragraph (1) of Paragraph 11 of the DPCO, 2013. However, this formula does not necessarily hold good in a case like the present one. NPPA was required to apply the methodology of determining the ceiling prices under Paragraph 4 of the DPCO, 2013 in a meaningful manner. It was, certainly, not precluded from selecting the appropriate data for determination of the ceiling price. This Court is of the view that notwithstanding the provisions of Sub-paragraph (1) of Paragraph 11 of the DPCO, 2013, the NPPA was not precluded from fixing the price for different pack size(s), if there were features that rendered it apposite to consider the formulation in different pack sizes as different products, for the purposes of price

fixation.

56. In view of the above, the impugned notification is set aside. Consequently, the impugned show cause notice and the impugned demand notice are also set aside. Since the price notification dated 13.11.2018 has been issued on the basis of the data as available in May, 2012/September, 2013, the ceiling price so fixed would also be applicable with effect from 14.06.2013, and nothing would preclude the respondent in recovering any amount overcharged, in any manner, by the petitioner considering the aforesaid ceiling prices.

57. The Fixed Deposit Receipts deposited by the petitioner with the registry of the Court are directed to be returned to the petitioner.

58. The petition is disposed of with the aforesaid terms. All pending applications are disposed of. The parties are left to bear their own costs.

