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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

\+ W.P.(C) 1922/2019 & CM Nos. 8947-8948/2019

TERUMO PENPOL PRIVATE LIMITED ..... Petitioner

Through: Mr S. Ganesh, Sr. Advocate with Mr Samudra Sarangi, Ms Shruti Raina and Mr Shahab Ahmad, Advocate.

versus

UNION OF INDIA AND ANR. ..... Respondents

Through: Mr Anurag Ahluwalia, CGSC with Mr Jitendra Kumar Tripathi, CGP for R-1 and R-2 alongwith Mr Alok Ranjan, Assistant Director of R-1 and R-2.

**CORAM:**
**HON'BLE MR. JUSTICE VIBHU BAKHRU**

**O R D E R**

**% 25.02.2019**

**VIBHU BAKHRU, J**

1. Issue notice. Mr Ahluwalia, learned counsel appearing for the respondents accepts notice. With the consent of the counsel, the petition is taken up for final hearing.

2. The petitioner has filed the present petition, *inter alia,* impugning an order dated 22.01.2019 (hereafter 'the impugned order') passed by the National Pharmaceutical Pricing Authority (NPPA), calling upon the petitioner to pay a sum of ₹16,44,47,476/- as the amount overcharged by the petitioner alongwith interest, as calculated

upto 31.01.2019.

3. The petitioner is engaged in the business of manufacturing certain devices including blood bags and blood transfusion sets, which it claims are sold in several countries. Essentially, the petitioner manufactures five devices, namely, (i) Trima Accel LRS Plasma Set; (ii) Trima Accel LRS Plasma RBC Set; (iii) Blood Administration Set; (iv) COBE Spectra Dual Needle Extended Life Platelet Set with LRS Chamber; and (v) COBE Spectra Therapeutic Plasma Exchange Set.

4. There is no dispute that the aforesaid items are covered under the definition of 'drugs' and they are amenable to the rigors of the Drug Price (Control) Order, 2013 (hereafter 'DPCO, 2013), even though they are not scheduled formulations.

5. Admittedly, the petitioner had raised the Maximum Retail Price (MRP) of the aforesaid drugs sometime in the year 2016. The increase in the MRP was in excess of the stipulated limit of 10% over and above the MRP, as existing in the previous twelve months. A tabular statement, indicating the MRPs of the said drugs as existing in the year 2015 and as increased in the year 2016, is as under:-

| # | Product | MRP 2015 | Revised MRP 2016 |
|---|---|---|---|
| 1. | Trima Accel LRS Plasma Set (80300) | 10300 | 12700 |
| 2. | Trima Accel LRS Plasma RBC Set (80400) | 10300 | 13500 |

| | | | |
|---|---|---|---|
| 3. | Blood Administration Set (TB*U800B) | 130 | 150 |
| 4. | COBE Spectra Dual Needle Extended Life Platelet Set with LRS Chamber (70300) | 10700 | 12700 |
| 5. | COBE Spectra Therapeutic Plasma Exchange Set (70500) | 10700 | 12700 |

6. In view of the above, the NPPA has concluded that the petitioner has fallen foul of paragraph 20(1) of the DPCO, 2013 and further computed the overcharged amount on the basis of the difference in the MRPs of the respective products and the quantity sold.

7. Mr Ganesh, learned senior counsel appearing for the petitioner has assailed the impugned order, essentially, on three fronts. First, he states that the petitioner had not increased the MRP of the products since several years and, therefore, was entitled to raise the said price by cumulatively taking into account the annual increase of 10%. He submitted that if an annual increase of 10% is factored in, then the increase in the MRPs of the products in question in the year 2016 would be well within the limits set as under paragraph 20(1) of the DPCO, 2013.

8. Second, that even though the petitioner has raised the MRP above the threshold limit of 10%, the actual sale price recovered by the petitioner was below the MRPs as fixed in the year 2015. He submits that in the circumstances, the increase in the MRPs was only on paper and, in effect, the petitioner has not realised any amount over and above the MRP, existing prior to the increase in the year 2016.

9. Third, it is submitted that the petitioner had informed NPPA regarding an increase in the MRP on 30.05.2017 and the impugned demand was issued on 22.01.2019 which, according to him, is beyond the reasonable period and, therefore, not sustainable.

10. Fourth, that the direction of the NPPA for restricting the MRP to the value, as was existing prior to the increase in the year 2016, for a further period of twelve months is contrary to the terms of DPCO, 2013.

11. Insofar as the first contention is concerned, that the petitioner is entitled to raise the MRP of a drug (other than the non-scheduled formulations) beyond the maximum limit of 10% over and above the MRP fixed in the preceding twelve months, by factoring in an annual increase of 10 % for the past period, is unsustainable. Paragraph 20(1) of the DPCO, 2013 is relevant and is set out below:-

> "**20. Monitoring the prices of non-scheduled formulations**-
>
> (1) The Government shall monitor the maximum retain prices (MRPs) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of

> maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months."

12. The language of paragraph 20(1) of the DPCO, 2013 is unambiguous. It proscribes the manufacturer from raising a Maximum Retail Price (MRP) beyond 10% of the MRP as existing during the preceding twelve months. There is no scope for the petitioner to make any adjustment on account of the preceding periods for which MRP has not been raised. It is also relevant to observe that the National Pharmaceutical Pricing Policy, 2012 brought about a paradigm shift in the administration of the ceiling prices from a cost based price regime to a price determined by the market force. Although, in terms of the DPCO, 2013, the ceiling prices are required to be fixed only for scheduled formulations, the prices of other drugs are also required to be monitored. This monitoring of the prices is also based on the market forces, and a manufacturer is free to fix the MRP with the restriction that the same cannot be increased beyond 10%, over and above the MRP fixed in the preceding twelve months. This is to ensure that the there is no runaway increase in the prices of the drugs. Thus, in cases where a manufacturer is compelled to peg up the MRP on market forces, it would militate against the very object of paragraph 20(1) of DPCO, 2013 to permit such a manufacturer to increase a price beyond 10% ,taking into account the period for which such manufacturer was constrained to peg the MRP at a price below the permissible increase.

13. Insofar as the contention, that the petitioner's challenge to the impugned order to the extent that it directs the petitioner to peg the MRP of the products to the price as prevailing in 2015 is concerned, it is submitted on behalf of the petitioner that it is not aggrieved by the same, as it has followed the said direction and reverted to the MRP as existing prior to the increase in 2016. It is stated that this was done as early as in February, 2018. In this view, the question whether the said direction was in conformity with paragraph 20 of the DPCO, 2013, is not required to be examined in this case. The issue whether such a direction could be issued is left open to be considered in an appropriate case.

14. The contention that the impugned order is passed beyond a reasonable period and therefore ought to be struck down, is also unpersuasive. Although, the Central Government is required to monitor prices on a continuous basis, the primary responsibility to ensure that the prices are not increased beyond the specified limit rests with the manufacturers. It is difficult to accept that manufacturers would be absolved of their liability merely on account of the NPPA not raising the demand under paragraph 20(2) of the DPCO, 2013, immediately.

15. Insofar as the petitioner's contention that it had not charged any amount over and above the permissible price is concerned, the same requires consideration. The petitioner has set out a tabular statement in its petition indicating that even though it had increased the MRPs for the drugs in question beyond a threshold of 10% in the year 2016,

the price charged were way below the MRP as fixed in the year 2015. The said tabular statement is set out below:-

| # | Product | MRP 2015 | ASP (2015-16) | Revised MRP 2016 | ASP (2016-17) | ASP (2017-18) |
|---|---|---|---|---|---|---|
| 1. | Trima Accel LRS Plasma Set (80300) | 10300 | 4956 | 12700 | 4829 | 4952 |
| 2. | Trima Accel LRS Plasma RBC Set (80400) | 10300 | 5088 | 13500 | `5375 | 5192 |
| 3. | Blood Administration Set (TB*Us00B) | 130 | 36 | 150 | 35 | 37 |
| 4. | COBE Spectra Dual Needle Extended Liffe Platelet Set with LRS Chamber (70300) | 10700 | 5349 | 12700 | 5363 | 5670 |
| 5. | COBE Spectra Therapeutic Plasma Exchange Set (70500) | 10700 | 5384 | 12700 | 5328 | 5510 |

16. In this view, even if it is accepted that the petitioner had fallen foul of the provisions of the paragraph 20(1) of the DPCO, 2013 inasmuch as it had increased the MRP beyond the limit of 10%, it is doubtful that any amount can be recovered in terms of paragraph 20(2) of the DPCO, 2013. This is so as, *prima facie*, the amount recoverable

is the amount actually overcharged and not the difference between two of the MRPs. This Court is not inclined to examine this controversy in this petition, as it would be apposite that the same should have been examined by the NPPA in the first instance.

17. In view of the above, the impugned order is set aside and the matter is remanded to the NPPA to consider the quantum of the amount recoverable as being overcharged by the petitioner. The petitioner is at liberty to file further documents to substantiate its contention that notwithstanding the increase of the MRP, it had, in fact, charged less than the MRP as fixed in the year 2015. The said documents may be filed within a period of four weeks from today. NPPA shall consider the same and pass an appropriate order after affording the petitioner an opportunity of hearing.

18. It is clarified that the NPPA is entitled to ascertain the veracity of the documents filed by the petitioner, including by seeking information from third parties. The pending applications stand disposed of.

**VIBHU BAKHRU, J**

**FEBRUARY 25, 2019**
**MK**